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IN THE

Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the U.S. Food and Drug Administration for use nationwide?

LIST OF PARTIES AND RULE 29.6 STATEMENT

All parties to the proceedings in the Supreme Court of Georgia are listed in the caption.

Wyeth is a publicly traded corporation. No publicly held corporation owns 10% or more of its outstanding shares.

Through its wholly owned subsidiaries, GlaxoSmithKline plc owns 100% of both SmithKline Beecham Corporation and GlaxoSmithKline Biologicals, S.A. No publicly held corporations own 10% or more outstanding shares.

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PETITION FOR A WRIT OF CERTIORARI

OPINIONS BELOW

The decision of the Supreme Court of Georgia is published at 668 S.E.2d 236, and is reproduced in the Appendix ("App.") at 1. The decision of the Georgia Court of Appeals, dated July 5, 2007, is published at 650 S.E.2d 585, and is reproduced at App. 19. The unpublished decision of the State Court of Fulton County, dated November 30, 2005, is reproduced at App. 33.

JURISDICTION

The Georgia trial court ruled that Section 22 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22, expressly preempted Respondents' design defect claims, and the court entered a partial summary judgment finally disposing of those claims. App. 42-49. The Georgia Court of Appeals reversed the trial court's order. App. 19. On October 6, 2008, the Georgia Supreme Court affirmed the Court of Appeals' order. App. 3-4. Upon Petitioners' application, on December 22, 2008, Justice Thomas extended the time to file a petition for a writ of certiorari in this case to and including March 5, 2009. This Court has jurisdiction under 28 U.S.C. § 1257(a).

The Georgia Supreme Court's decision is a final judgment for the purposes of 28 U.S.C. § 1257(a). *See Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975); *see also Belknap, Inc. v. Hale*, 463 U.S. 491,

497 n.5 (1983) (allowing review of a state court determination that state causes of action were not preempted by federal law). A decision not to review the Georgia Supreme Court's decision now will "seriously erode" the federal public health policies of the Vaccine Act. *Cox Broad. Corp.*, 420 U.S. at 483. The Vaccine Act's preemption of civil liability is integral to ensuring adequate supplies of vaccines necessary to protect the public from infectious disease. *See* H.R. Rep. No. 99-908, at 7 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6348 [hereinafter "H.R. Rep. at __, 1986 U.S.C.C.A.N. at __"].

This case satisfies all three criteria necessary to justify immediate review of a state supreme court decision that threatens federal policy. *See Cox Broad. Corp.*, 420 U.S. at 482-83. First, the Georgia Supreme Court has finally determined that the Vaccine Act does not categorically preempt design defect claims. Second, the design defect claims could be resolved on other grounds on remand—such as the failure to prove, after trial, that the alleged injury was caused by the vaccines—depriving Petitioners of any opportunity to seek review of the preemption ruling. Third, if this Court reverses the Georgia Supreme Court's decision, the design defect claims will be conclusively resolved as preempted and will not be further litigated. The Court should not delay addressing this pressing preemption question, because the Georgia Supreme Court's decision invites litigation larger in scope than the onslaught two decades ago that impelled Congress to adopt the Vaccine Act.

CONSTITUTIONAL AND STATUTORY PROVISIONS

This case involves application of the Supremacy Clause of the United States Constitution, art. VI, § 1, cl. 2, which provides as follows:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The case revolves around the interpretation of 42 U.S.C. § 300aa-22, which provides, in relevant part, as follows:

> **§ 300aa-22. Standards of responsibility**
>
> (a) General Rule
>
> Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was

accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

INTRODUCTION

Congress narrowly averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-1 *et seq.* (the "Vaccine Act" or "Act"). In a decision that avowedly rejects the position of every other jurisdiction to rule on the issue, the Georgia Supreme Court has invited that crisis back.

The crisis was an alarmingly unstable vaccine supply. As Congress declared, "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. But vaccine manufacturers labored under the strain of crushing defense costs and potential liability from several hundred product liability cases pressing "design defect" claims—i.e., claims that the manufacturer should have adopted a vaccine design different from, and allegedly safer than, the Food and Drug Administration ("FDA") approved design. The litigation strain was driving vaccine manufacturers out of the market, causing vaccine shortages, and threatening a resurgence of infectious disease. Congress stabilized the vaccine market—and averted the public health crisis—by shielding vaccine manufacturers from tort liabilities (with specified exceptions), and creating a reliable and speedy no-fault remedy administered by a special federal court (colloquially known as "Vaccine Court").

The liability shield, which is at issue in this case, is in Section 22(b)(1) of the Vaccine Act. That

provision expressly preempts *all* civil liability "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Outside of Georgia, every court to rule on the Vaccine Act's preemption provision has correctly interpreted it to categorically preempt all claims for vaccine-related injuries unless the vaccine at issue contained a manufacturing defect (i.e., was not "properly prepared") or was inadequately labeled (i.e., was not accompanied by "proper directions and warnings"). Thus, each one of these courts rejected attempts by plaintiffs to circumvent the Act through state law "design defect" claims.

In this case, however, the Georgia Supreme Court rejected the prevailing categorical rule. It held that Section 22(b)(1) does not preclude design defect claims unless the manufacturer demonstrates, case by case, that there *was no safer design* that could have avoided the injury. Under this rule, judges and juries in every case, in every state, would second-guess the balance that the FDA and several other federal agencies strike between vaccine safety and efficacy. To reach this conclusion, the Georgia Supreme Court improperly isolated Section 22(b)(1)'s language about "side effects that were unavoidable" from the rest of the sentence, disregarding Congress's intent to characterize a side effect from an FDA-approved vaccine as "unavoidable" and therefore not subject to lawsuits *as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." The court also disregarded the legislative history confirming that

Section 22(b)(1) was intended to provide complete immunity from suit for claims based on design.

If the Georgia Supreme Court's interpretation of the preemption provision stands, tort litigation will once again swamp vaccine manufacturers in a way that could make the deluge of 1986 seem like a trickle. There are currently more than 4,900 claims pending in an "Omnibus Autism Proceeding" in Vaccine Court. Like the claim in this case, many of these thousands of claims are premised on the notion that a child's autism was caused by FDA-approved vaccines and could have been avoided by using a different, purportedly safer design.

Under the Georgia rule, every one of these claimants would have the option to reject the Vaccine Court's judgment and collaterally challenge the FDA's approval of a vaccine's design before a jury. The few remaining vaccine manufacturers will face the expense and uncertainty Congress averted 20 years ago—but this time, dialed up by an order of magnitude. The threat to the nation's vaccine supply and to the development of new vaccines is too grave to leave for another day. This Court should review the Georgia Supreme Court's decision now.

STATEMENT OF THE CASE

A Stable Vaccine Supply Is Critical To Public Health

As recently as the middle of the 20th century, infectious diseases crippled, or even killed, tens of thousands of children a year. Into the 1950s, polio killed nearly 1,900 Americans annually, and paralyzed over 16,000. CDC, *Ten Great Public*

Health Achievements—United States, 1900-1999, 48 *MMWR* 241, 246 (Apr. 2, 1999). Measles afflicted over half a million victims a year, killing more than 400. *Id.* The highly contagious pertussis disease (commonly known as whooping cough) infected over 140,000 victims. *See* Walter A. Orenstein et al., *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Aff. 601, 602 (2005).

Over the decades, public health programs to vaccinate and immunize whole populations have virtually vanquished all these infectious diseases. Smallpox was literally eradicated worldwide by 1977. CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 *MMWR* 241, 246 (Apr. 2, 1999). Polio, diphtheria, and tetanus were effectively eliminated in the United States. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. By the 1980s, whooping cough, measles, mumps, and rubella had been subdued by more than 98% of their peak levels. *National Childhood Vaccine Injury Compensation Act of 1985: Hearing on S. 827 Before the S. Comm. on Labor and Human Resources*, 99th Cong. 145 (July 18, 1985). Vaccines made these public health triumphs happen. It was no exaggeration when the congressional committee that reported on the Vaccine Act observed: "Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken." H.R. Rep. at 4, 1986 U.S.C.C.A.N. at 6345. But, as Congress also recognized, the program requires constant attention: the continued suppression of infectious disease depends upon ongoing universal vaccination, which

depends, in turn, on a stable supply of vaccines. *Id.* at 7, 1986 U.S.C.C.A.N. at 6348.

Vaccine Litigation Causes a Public Health Crisis

In the mid-1980s the requisite vaccine supply was teetering on the brink of disaster. The root cause was a proliferation of tort cases against vaccine manufacturers. The vast majority of the cases targeted the combined pediatric vaccine for diphtheria, tetanus, and pertussis ("DTP"). Plaintiffs brought design defect claims alleging that the only FDA-approved DTP vaccine design was unreasonably dangerous, and thus defective.

The litigation threat precipitated an exodus from the vaccine market. "The number of childhood vaccine manufacturers . . . declined significantly," *id.* at 4, 1986 U.S.C.C.A.N. at 6345, while the few that remained began "to question their continued participation in the vaccine market," *id.* at 7, 1986 U.S.C.C.A.N. at 6348. As of the end of 1984, two of the three domestic commercial manufacturers of the DTP vaccine had withdrawn from the market. *See Staff of Subcomm. on Health and the Environment, 99th Cong., Childhood Immunizations* 68 (Sept. 1986) [hereinafter "Subcomm. Rep."]. The fragility of supply was shown when the one remaining manufacturer experienced production problems. *Id.* at 69.

This was the "unstable and unpredictable childhood vaccine market" Congress observed. H.R. Rep. at 5, 1986 U.S.C.C.A.N. at 6346. There was "a short term crisis of availability of DTP vaccine."

Subcomm. Rep. at 68. The shortage became so dire that the Centers for Disease Control and Prevention ("CDC") recommended stretching out the vaccination schedule—diluting children's protection. *Id.* at 69.

Congress sounded the alarm: The "withdrawal of even a single [additional] manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps a resurgence of preventable disease." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348.

Congress Averts the Crisis with the Vaccine Act

Congress responded to the public health crisis decisively—by passing the Vaccine Act. The Vaccine Act is an intricate and comprehensive federal scheme to insulate the remaining (and new) vaccine manufacturers from litigation, while both compensating the few individuals who suffer adverse side effects and fostering the development of safer and more effective vaccines.

Shielding vaccine manufacturers from tort litigation. The element of the statutory scheme that protects vaccine manufacturers from the potentially ruinous burden of litigation, which is at the heart of this petition, is Section 22(b)(1). It provides, in full:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was

> properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). This preemption clause preserves a limited tort remedy against a manufacturer for injuries caused by a vaccine not made according to its FDA-approved formula or that does not provide proper directions and warnings for use.[1] *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (claimants who "cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings should pursue recompense in the [administrative] compensation system, not the tort system."). Such claims, however, did not drive the litigation crisis. The question in this case is whether the reference to "unavoidable" injuries somehow leaves open the possibility of liability for design defect claims—the very sorts of claims that were central to the litigation in the 1980s.

Whatever the answer to this question, *any* claim for a vaccine-related injury must begin with a petition for compensation in the Vaccine Court, which is an adjunct to the Court of Federal Claims. 42 U.S.C. §§ 300aa-11(a)(2), 12(c), 21(a). The Secretary of the United States Department of Health and Human Services ("HHS") appears as a respondent: vaccine manufacturers are not parties

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[1] The Vaccine Act allows a presumption that FDA-approved directions and warnings are adequate. 42 U.S.C. § 300aa-22(b)(2). That provision, and the scope of its effect upon failure-to-warn claims, is not at issue in this petition.

to Vaccine Court litigation. *See id.* § 300aa-12(b). Compensation, paid out of the proceeds from a vaccine tax, is awarded on a no-fault basis. *Id.* §§ 300aa-13, 14, 15(i). A Vaccine Court claimant need not prove that the vaccine was in any way defective or that the injury could have been avoided through a safer design or otherwise—as tort law would require—but only that there is a causal link between the injury and the vaccine. *See id.* § 300aa-13. Congress designed this mandatory federal remedy "to work faster and with greater ease than the civil tort system." *Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995).

For vaccine-related injury claims preempted by Section 22(b), the Vaccine Court remedy (with its attendant appeals) is the only remedy available. For those vaccine-related injury claims that may be pursued in a civil action, the claimant who exhausts the Vaccine Court process has a choice to make: accept the Vaccine Court's judgment, or elect against it and litigate from square one in court, subject to several substantive and procedural constraints. *See* 42 U.S.C. § 300aa-21.

The National Vaccine Program. The Vaccine Act also established a National Vaccine Program to "promote the development of childhood vaccines that result in fewer and less serious adverse reactions," and to "assure improvements in . . . the licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* § 300aa-27(a)(1)-(2). Through this program, lodged in HHS, nearly a dozen federal agencies ("NVP Agencies") collaborate "to achieve optimal

prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." *Id.* §§ 300aa-1, 2; HHS/Public Health Service/National Vaccine Program Office, *The U.S. National Vaccine Plan – 1994*, at 3 (1994) (listing responsibilities of various agencies).

One of the key agencies in the program is the FDA, which regulates the formulation, production, and labeling of childhood vaccines. *See* 21 U.S.C. § 301 *et seq.*; 42 U.S.C. § 262(c); 21 C.F.R. § 600 *et seq.* An FDA-licensed vaccine must be made according to its approved formula. *See* 21 C.F.R. §§ 601.2, 601.12. The FDA "makes approval decisions based not on abstract estimation of [a prescription product's] safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006). The FDA strikes the delicate balance between safety and efficacy, ever aware that any vaccine inevitably causes some adverse reactions and that making a vaccine safer can sometimes compromise its efficacy. *Cf. Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008) (describing FDA's balancing of medical device's costs and benefits). Even after approval, the FDA, the CDC, and the National Institutes of Health all monitor safety data from the vaccine manufacturers and several independent sources. *See* 42 U.S.C. § 300aa-2(a)(2)-(3).

Trial Court Dismisses Plaintiffs' Design Defect Claims

Respondents (referred to here as "plaintiffs") are the parents of an autistic child. They claim that FDA-approved vaccines caused their child's autism—pinning the blame specifically on thimerosal, the preservative used in the FDA-approved formulations. While allegations of this sort have swept through the media and the internet, every reputable scientific body and governmental agency that has studied the question—including the FDA and CDC—has rejected any linkage between vaccines and autism. *See, e.g.*, FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/cber/vaccine/thimerosal.htm. (last modified Jan. 14, 2009) (stating that FDA "conducted a comprehensive review of the use of thimerosal in childhood vaccines," and concluding that there was "no evidence of harm from the use of thimerosal as a vaccine preservative, other than local hypersensitivity reactions"); CDC, *Mercury and Vaccines (Thimerosal)*, http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm (last modified Feb. 8, 2008) ("There is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor effects like redness and swelling at the injection site.").

Most notable and comprehensive among the scientific reviews was the report of a panel of world-renowned experts appointed by the National Academy of Science's Institute of Medicine, which decisively declared that "**the evidence favors rejection of a causal relationship between thimerosal containing vaccines and autism.**"

Immunization Safety Review Committee, Board on Health Promotion and Disease Prevention, Institute of Medicine, *Immunization Safety Review: Vaccines and Autism* 7 (2004) (emphasis in original).

Plaintiffs presented their claim to the Vaccine Court, which had already instituted an Omnibus Autism Proceeding. The omnibus proceeding will decide—for some 4,900 like claims—whether there is a causal link between childhood vaccines and autism. On February 12, 2009, the Vaccine Court issued opinions in three test cases considering claimants' theory that the Measles-Mump-Rubella ("MMR") vaccine, in combination with thimerosal-containing vaccines, could cause autism. *See Cedillo v. Sec'y of HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009); *Hazlehurst v. Sec'y of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009); *Snyder v. Sec'y of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009). In nearly 700 pages of detailed analysis, the Vaccine Court rejected that theory. The Vaccine Court is expected to issue causation rulings later this year in test cases considering claimants' theory that thimerosal-containing vaccines *alone* could cause autism.

Rather than await a ruling on the merits in the omnibus proceeding, plaintiffs here invoked a provision of the Vaccine Act authorizing them to opt out of Vaccine Court and file a lawsuit in court if the Vaccine Court does not resolve the petition within 240 days. *See* 42 U.S.C. § 300aa-21(b)(1). Plaintiffs sued the vaccine manufacturers (Petitioners here) in state court in Georgia. They asserted claims for strict liability, negligence, fraud, negligent misrepresentation, and breach of warranty. App. 36.

As relevant here, their central theory of liability is design defect—that the FDA-approved designs for the vaccines administered are defective, and the manufacturers should not have used the thimerosal preservative as approved by the FDA.

The vaccine manufacturers moved for summary judgment on the basis that the Vaccine Act preempted plaintiffs' claims. App. 34-35. The trial court entered summary judgment, dismissing the design defect claims. The court reasoned that "Congress [did not] leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that preempts design defect claims." App. 45. This ruling was consistent with the conclusions other courts had reached on the preemption of vaccine design defect claims. App. 43. The trial court denied summary judgment on the other claims. App. 55.

Georgia Appellate Courts Reverse

The Georgia Court of Appeals reversed. The court acknowledged that "when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt [design defect claims] becomes clear." App. 30. Nevertheless, the court felt compelled to disregard congressional intent because it found it could interpret the statutory language in two competing ways: (1) the statute preempts all design defect claims; or (2) design defect claims are preempted "only if the side effects are determined to be unavoidable on a case-by-case basis." App. 29-30. The Court of Appeals believed that this Court's

decision in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), obliged it "to accept the reading of an express preemption statute that disfavors preemption," and to focus on "the statutory language alone," without regard to structure, purpose, or legislative history. App. 28. The court observed that its denial of preemption "is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in *Bates*." App. 31.

The Georgia Supreme Court granted the vaccine manufacturers' petition to review the Court of Appeals' ruling that the Vaccine Act did not categorically preempt plaintiffs' design defect claims. App. 3. The Georgia Supreme Court rejected the Court of Appeals' logic—specifically, its peculiar reading of *Bates*—but upheld the result on different grounds. App. 3-4. It held that even in light of the Vaccine Act's structure and legislative history, there was no "clear and manifest congressional purpose" to preempt all design defect claims. App. 18.

The Georgia Supreme Court recognized that its ruling conflicted with all of the other courts to have decided the issue (except the Georgia Court of Appeals). App. 7. But it staked out that position for Georgia, "at least until the Supreme Court of the United States has spoken on the issue." App. 18.

REASONS FOR GRANTING THE PETITION

This case presents a stark choice between two rules. Outside of Georgia, courts have ruled that Congress categorically preempted all state-law claims asserting that the manufacturer should have

adopted a vaccine design that was safer than the one the FDA approved. Properly interpreting Section 22(b)(1), these courts have uniformly allowed only suits based on the theory that the vaccine was improperly prepared or labeled. The Georgia Supreme Court reached the opposite conclusion. It held that Congress preempted tort suits only if the manufacturer demonstrates factually, in the specific case presented, that there was *no safer design* that could have avoided the injuries at issue. According to the Georgia Supreme Court, the express preemption clause does not eliminate the need for discovery and trial because Congress intended to leave expert regulatory determinations about vaccine design open to jury re-examination.

In so holding, the court also did violence to the complex and interrelated purposes and structure of the Vaccine Act. It effectively eliminated one of the most important benefits of the Vaccine Act bargain to vaccine companies by subjecting them once again to costly litigation over matters of vaccine safety that Congress has entrusted to federal health agencies. There is no protection from litigation cost if preemption occurs only at the end of discovery and trial when a jury finds, in a specific case applying state law, that the vaccine had the safest possible design for the injury at issue.

As is demonstrated more fully below, the differences between these two judicial interpretations could not be starker, and the conflict is entrenched and intractable—which is reason alone to grant certiorari. *See infra* Point II. But the main reason to grant certiorari is that the choice between the two approaches is a matter of profound national

importance. *See infra* Point I. The Georgia Supreme Court's approach is so demonstrably wrong, *see infra* Point III, and the threat to public health is so real and imminent, that the issue must be resolved now, without further percolation.

I. THIS CASE IS OF PROFOUND NATIONAL IMPORTANCE BECAUSE THE GEORGIA SUPREME COURT'S RULING UNDERCUTS CONGRESS'S LIMITS ON CIVIL LIABILITY AND THREATENS THE NATION'S VACCINE SUPPLY.

The Court should grant this petition because the Georgia Supreme Court's rule threatens public health by inviting a litigation deluge even bigger than the one that spurred Congress to urgent action in 1986. It does not take any imagination to foresee the consequences. First, as in 1986, the Georgia rule will de-stabilize the vaccine market, which could lead to potentially devastating vaccine shortages. Second, it could stall the development of new life-saving vaccines.

The threat to the vaccine supply. The litigation surge that Congress averted in 1986 was nothing compared to the tidal wave that the Georgia Supreme Court's ruling invites. The graph on page 21 shows how many cases it takes to make a crisis. In 1986, when vaccine litigation peaked, plaintiffs were filing hundreds of cases a year. Over 250 of the cases then pending related to the DTP vaccine. Geoffrey Evans, *Update on Vaccine Liability in the*

United States, 42 Clinical Infectious Diseases S130, S134 (2006). [2]

The costs of defending these hundreds of lawsuits were crushing, and increasing. *See* Subcomm. Rep. at 87; H.R. Rep. at 6, 1986 U.S.C.C.A.N. at 6347. Potential liability also loomed over the industry. In 1984, one major vaccine manufacturer (a corporate ancestor of Petitioner Wyeth) estimated that its potential liability from DTP vaccine lawsuits was 200 times its annual sales for the vaccine. Subcomm. Rep. at 69. The litigation costs and potential liability spawned real-world consequences: an unstable and constricted vaccine supply.

The Vaccine Act dramatically altered the litigation status quo through the preemption of certain tort claims and the no-fault compensation program. In just two decades, the compensation fund has awarded more than $1.8 billion to over 2,200 families and individuals. HHS, *HRSA Awards Contract to Study Adverse Events in Childhood Vaccines* (Oct. 23, 2008), http://newsroom.hrsa.gov/releases/2008/vaccinestudy.htm. As the graph on page 21 illustrates, litigation against DTP manufacturers slowed to a trickle after the law took effect. The same is true for cases involving other vaccines. *See id.* The post-Vaccine Act litigation that has been filed to date has been less costly. No case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial – much less to

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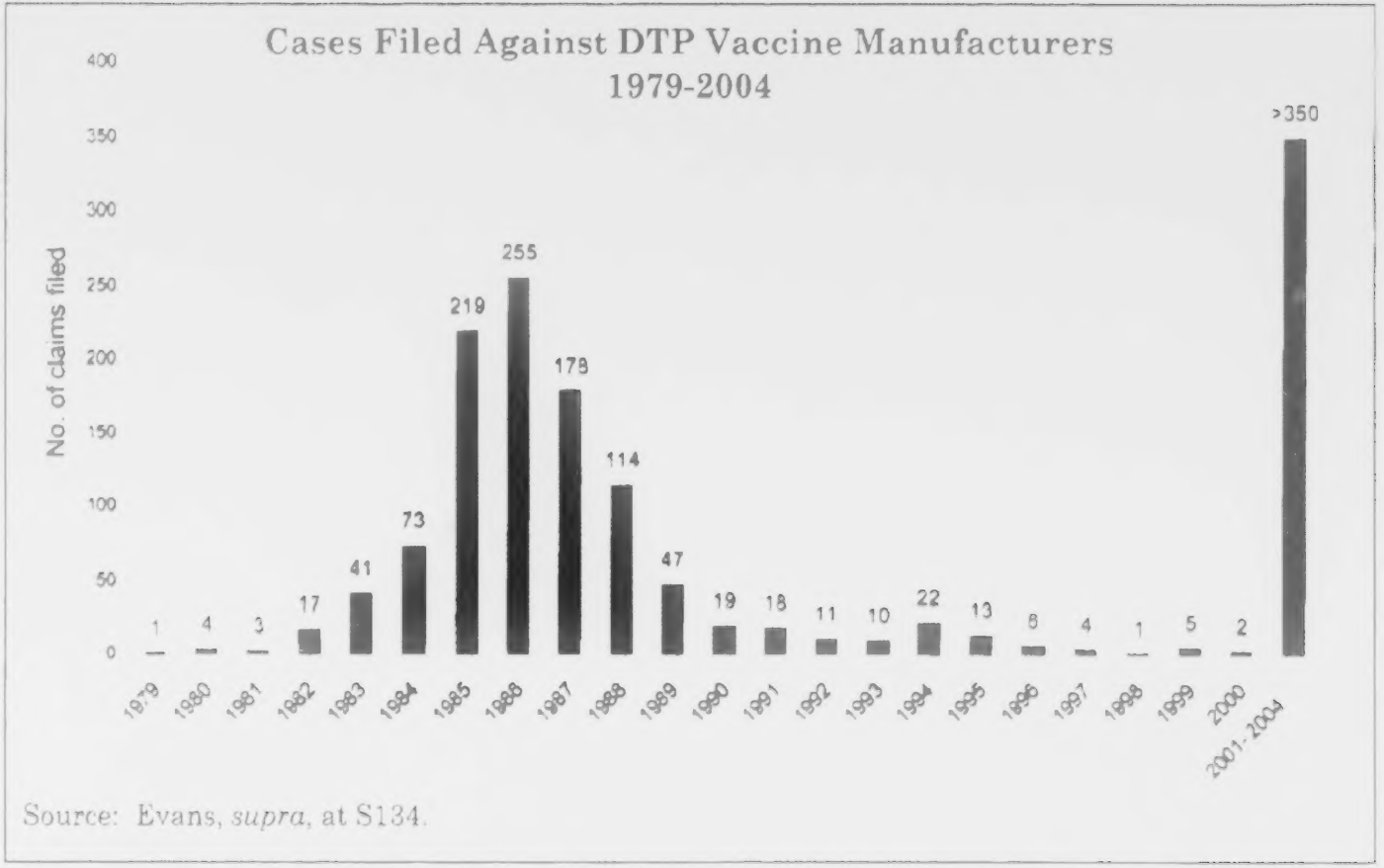
[2] For the most part, the DTP lawsuits alleged that the vaccine's design was defective because the pertussis component caused permanent neurological damage.



Source: Evans, *supra*, at S134.

verdict—in the two decades since the Vaccine Act became effective.

Since 2001, however, plaintiffs have increasingly tested what seemed to be settled limits on litigation. Civil suits against vaccine manufacturers are up again. The filings now number over 350. Evans, *supra*, at S134. Some of these suits involve multiple plaintiffs. Almost all of these suits include clones of this design defect claim. In Georgia alone, more than 20 cases like this one are pending, and Georgia's rule may attract even more suits against vaccine manufacturers.

Nationwide filings are also bound to spike, as plaintiffs, emboldened by the Georgia ruling, try to replicate the results in other states. The Vaccine Court's February 12 rulings rejecting claimants' general causation theory in MMR-thimerosal combined cases (*supra* p. 15) foreshadows a denial of Vaccine Act compensation to those claimants and also to those that cite only thimerosal-containing vaccines as the cause of their injuries. A civil action will be their next and only remaining—avenue for relief. If any significant portion of the 4,900 vaccine-autism claimants in Vaccine Court exercise their statutory right to reject that court's judgment and file a civil action, hundreds or even thousands of new vaccine cases will flood the courts. The numbers could easily overtop the level of filings in 1986. Without the categorical preemption of vaccine design claims as intended by Congress, Vaccine Court could be reduced to a mere checkpoint plaintiffs pass through on their way to civil court.

As was true in 1986, the most immediate concern is not the potential liability, but the cost of defending hundreds or thousands of lawsuits. Even if judges and juries eventually accept the prevailing scientific view that vaccines do not cause autism (*see supra* pp. 14-15), the litigation expense will be even more crushing than it was back in 1986. To reach the stage in a litigation at which the discredited causation hypothesis could be challenged, a vaccine manufacturer would have to endure expensive discovery—thousands of times over if the deluge materializes.

This deluge could lead to the very same dangerous situation that existed in the mid-1980s—vaccine manufacturers abandoning the market, which in turn yields vaccine shortages and exposes the nation to the renewed threat of an epidemic. The number of vaccine manufacturers has not increased. In the United States market today, as in 1986, there is still just one manufacturer for the polio vaccine, one for MMR, and two for the DTP vaccine. *Compare* H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348, *with* FDA/CBER, *Thimerosal in Vaccines*, http://www.fda.gov/CBER/vaccine/thimerosal.htm (last modified Jan. 14, 2009). The concerns that motivated Congress in 1986 would reappear: The loss of even one more vaccine manufacturer "could create a genuine public health hazard." H.R. Rep. at 7, 1986 U.S.C.C.A.N. at 6348. The same concerns that compelled Congress to intervene and pass the Vaccine Act in the first place, should compel the Court to intervene and verify which interpretation of the Act is correct—the one that has fulfilled Congress's goal in achieving vaccine stability or the

one that will revive the crisis Congress averted over two decades ago.

The threat to vaccine development. While the Congress that passed the Vaccine Act was most urgently concerned about the public health consequences of the litigation crisis, it recognized the need for vigilance in developing new vaccines and improving existing ones. Congress noticed that vaccine manufacturers were limiting their investment in research and development for two primary reasons. First, the cost of developing a new vaccine is prohibitive: The investment could be as much as 30% of the industry's total annual sales. Subcomm. Rep. at 72. Second, the staggering potential tort liability for vaccine-related injury claims, notwithstanding an FDA-approved vaccine design, could easily lead a drug manufacturer to conclude the investment is not worth the price. *Id.*

While Congress directed several federal agencies to supplement the vaccine research being conducted by the industry, Congress understood that efforts would fail unless the agencies collaborated closely with the industry. *See* H.R. Rep. at 11, 1986 U.S.C.C.A.N. at 6352. The public-private collaboration Congress envisioned has had astounding success. Since 1986, the collaboration has yielded seven new vaccines now on the routine childhood immunization schedule: hepatitis B; varicella; pneumococcal disease; influenza; hepatitis A; meningococcal disease; and rotavirus. *Compare* CDC, *Recommendation of the Immunization Practices Advisory Committee New Recommended Schedule for Active Immunization of Normal Infants and Children*, 35 MMWR 577 (Sep. 19, 1986), *with*

CDC, *Recommended Immunization Schedules for Persons Aged 0-18 Years—United States, 2008*, 57 MMWR Q1 (Jan. 11, 2008).

All three of the vaccines being challenged in this case were products of the National Vaccine Program. Among them is Wyeth's vaccine for *Haemophilus influenzae* type B ("Hib"), which is an especially good illustration of the Program's success. Hib—the leading cause of childhood bacterial meningitis and postnatal mental retardation—formerly afflicted some 20,000 children a year. *See* CDC, *Ten Great Public Health Achievements—United States, 1900-1999*, 48 MMWR 241, 246 (Apr. 2, 1999). In the decade after Wyeth introduced its vaccine for infants, the incidence of Hib invasive disease in children under five fell 99%. *See* Kashif Iqbal et al., *Haemophilus influenzae Type b Invasive Disease*, 2-1 (2008), http://www.cdc.gov/vaccines/pubs/surv-manual/chpt02-hib.pdf.

The work on vaccines is far from over. The need remains for improvement and invention. To take one example, current influenza and pneumococcal vaccines must be adapted to battle new strains of the disease. *See* Laura Beil, *Worrisome Infection Eludes a Leading Children's Vaccine*, N.Y. Times, Oct. 14, 2008. Beyond the diseases that currently afflict our population, public health authorities must guard against foreign invaders. A single peripatetic host carrying a foreign disease could spark an epidemic here, just as a Severe Acute Respiratory Syndrome ("SARS") epidemic spread from China to 37 countries in a matter of weeks. *See* Richard D. Smith, *Responding to Global Infectious Disease Outbreaks: Lessons from SARS on the Role of Risk Perception*,

Communication and Management, 63 Soc. Sci. & Med. 3113 (2006). A robust research program that explores new vaccines is our best protection from these intruders.

Congress worried that a wave of product liability litigation would deter investment in new or improved vaccines and undermine collaboration with federal agencies. That same concern is equally real now. Once again, the choice is as grave as it is clear: a legal rule that will extend the collaborative vaccine success over the past two decades versus the Georgia rule, which will encourage the pharmaceutical industry to withdraw from vaccine research.

II. THE SPLIT OVER WHETHER THE VACCINE ACT CATEGORICALLY PREEMPTS ALL DESIGN DEFECT CLAIMS IS ACKNOWLEDGED AND INTRACTABLE.

The conflict between the Georgia Supreme Court and the majority rule is stark, acknowledged, and intractable.

All courts outside of Georgia that have ruled on the issue have held that the Vaccine Act's preemption clause expressly preempts all design defect claims. *See Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845-46 (Sup. Ct. 2003), *aff'd*, 810 N.Y.S.2d 506 (App. Div. 2006), *leave denied*, 857 N.E.2d 1137 (N.Y. 2006) (table); *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430, 444-46 (E.D. Pa. 2007), *appeal docketed*, No. 07-3794 (3d Cir. argued Sep. 11, 2008); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 299-303 (E.D. Pa. 2007); *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664-66

(S.D. Tex. 2004); *Wright v. Aventis Pasteur, Inc.*, No. 3861, 2008 WL 4144386 (Pa. Ct. Com. Pl. Aug. 27, 2008), *appeal docketed*, No. 336 EDA 2008 (Pa. Super. Ct.). These courts have concluded that the Vaccine Act expressly preempts all liability of vaccine manufacturers unless the claimed injury could have been avoided by proper preparation or proper directions and warnings. "If the alleged defect that caused the claimant's injury does not fall into one of [those] two enumerated categories, the defect is considered 'unavoidable,' and the claimant's tort claim is barred." *Blackmon*, 328 F. Supp. 2d at 664.[3] These courts reach this conclusion as a matter of plain language, legislative history, and statutory structure.

The Georgia Supreme Court reached the opposite conclusion when it held that the Vaccine Act's preemption clause "clearly does not preempt all design defect claims against vaccine manufacturers," App. 15, "but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular

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[3] This Court's recent decision in *Wyeth v. Levine*, No. 06-1249, 2009 WL 529172 (U.S. Mar. 4, 2009), is not relevant to the question presented by this petition. The Court held in *Levine* that the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, did not impliedly preempt plaintiff's failure-to-warn claim relating to the prescription drug Phenergan. *Id.* at *13. The question presented by this petition, however, is whether Congress intended for 42 U.S.C. § 300aa-22(b)(1) of the Vaccine Act to expressly preempt all design defect claims for childhood vaccines.

vaccine were unavoidable." App. 4. In so holding, the Georgia Supreme Court cited and analyzed the cases in the majority camp, but found them "erroneous[]" and "mistaken[]" on each point—statutory language, legislative history, and structure. App. 8-12, 16-18.

In short, courts presented with the same tort claims, the same statute, and the same legislative history have come to diametrically opposite conclusions. The conflict is entrenched and acknowledged, and the Georgia Supreme Court has declared that its decision would remain the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." App. 18. Until then, vaccine manufacturers sued in Georgia (or in other states that may follow Georgia's lead) will not have the benefit of the preemption defense—and the conflict among the lower courts will remain.

Admittedly, the conflict presented here has not ripened to the level this Court typically prefers—a conflict between a state's highest court and a federal court of appeals—at least not at this moment. The preferred sort of conflict may well materialize while this petition is pending. The Third Circuit is poised to issue an opinion on the issue presented here, as it is now reviewing a district court opinion holding that the Vaccine Act categorically preempts all design defect claims. *See Bruesewitz*, 508 F. Supp. 2d at 446, *appeal docketed*, No. 07-3794 (3d Cir.). The Third Circuit heard argument in mid-September, 2008, and its opinion is imminent.

In any event, for reasons already described, *see supra* Point I, the issue warrants this Court's

immediate attention. Neither Petitioners nor the public have the luxury to allow the issue to percolate further, because the Georgia Supreme Court's position will precipitate a litigation deluge that will threaten public health.

III. THE GEORGIA SUPREME COURT ERRED IN HOLDING THAT THE VACCINE ACT DOES NOT PREEMPT ALL DESIGN DEFECT CLAIMS.

Review is also warranted because the Georgia Supreme Court erred at every step of its analysis—on its construction of the language of the preemption provision, the legislative history, and the structure of the Vaccine Act. The Court read the statute in a truncated fashion, improperly fixating upon Section 22(b)(1)'s language about "side effects that were unavoidable" and disregarding the remainder of the sentence. By ignoring those words, it arrived at a construction that betrayed Congress's intent that a side effect from an FDA-approved vaccine be considered "unavoidable" *as long as* "the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). In other words, the provision immunizes vaccine manufacturers from *all* liability in any civil action for vaccine-related injury regardless of legal theory, unless the injury at issue could have been avoided by proper preparation or "proper directions and warnings"—with the proviso that directions and warnings are ordinarily presumed to be "proper" if they were FDA approved. 42 U.S.C. § 300aa-22(b)(2).

Like the other courts to address the issue, the Georgia Supreme Court recognized that Section 22(b)(1)'s language derives from the well-known Comment k to Section 402(A) of the Restatement (Second) of Torts. App. 7. Comment k protects a certain class of products from strict liability: products deemed to be "unavoidably unsafe" because they carry an inherent risk of injury. Restatement (Second) of Torts § 402A cmt. k. While various states have taken different paths to determining whether products are entitled to the protection of Comment k, the Georgia Supreme Court erred in failing to recognize that Congress made the blanket determination that childhood vaccines are "unavoidably unsafe" and should be categorically exempt from liability for injuries resulting from inherent risks. *See* H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (stating that the principle of Comment k "appl[ies] to the vaccines covered in the [Act] and that such products not be the subject of liability in the tort system").

As to legislative history, the courts adhering to the majority view—and even the Georgia Court of Appeals, App. 30—have correctly pointed out that congressional intent could not be clearer. The legislative history "indicates rather clearly the Committee's intent to relegate design defect claims to the [Vaccine Court] compensation system." *Blackmon*, 328 F. Supp. 2d at 665; *see also Militrano*, 810 N.Y.S.2d at 508 (holding that the "Committee's discussion of the issue clearly establishes Congress' determination that the Comment k defense bars all [vaccine design defect] claims"). The key committee report explains:

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was *improperly prepared* or that it was *accompanied by improper directions or inadequate warnings* [they] *should pursue recompense in the compensation system, not the tort system.*

H.R. Rep. at 26, 1986 U.S.C.C.A.N. at 6367 (emphasis added).

The Georgia Supreme Court erred in relying instead on a post-enactment legislative statement that other courts correctly ignored. *See* App. 13-14. Such subsequent legislative history is "a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). That cautionary note is especially apt here. The 1987 committee report on which the court relied to discern Congress's intent a year earlier related to the funding of the Act. The funding amendments had nothing to do with the preemption clause's limitations on liability that govern post-Vaccine Court civil actions.

Perhaps the Georgia Supreme Court's most fundamental error, however, was to ignore the statutory structure and context for Section 22. The

Georgia Supreme Court declared, without any elaboration, that its analysis was "consistent with the structure and purpose of the Vaccine Act." App. 15 (citation omitted). In fact, the decision is at war with the Act's structure and purpose. While the Georgia Supreme Court's ruling assumes that permitting litigation over vaccine designs would lead to safer vaccines, *see* App. 17, Congress chose a very different policy. Congress saw the consequences of leaving vaccine injury litigation to a tort regime like the one the Georgia Supreme Court adopted here: a dangerously unstable vaccine market and the constant threat of a public health crisis.

The Georgia Supreme Court overlooked the perfect symmetry between a single federal standard for vaccine design and the Vaccine Act's complementary components. Congress commits the controlling evaluation of vaccine design to the FDA, with the input, monitoring, and enhancement of other NVP Agencies. This decision to empower a network of federal agencies to strike the optimum balance between safety and efficacy complements the decision to allow any person injured by a vaccine approved for nationwide use to seek no-fault compensation in the Vaccine Court, without having to prove (as state tort-law would require) that the safety-efficacy trade-off was unreasonable. With that uncommonly generous compensation program in place, Congress preempted tort litigation premised on the view that the vaccine that the FDA approved, and the other NVP Agencies vetted and monitored, should have been safer.

When Congress created this comprehensive scheme, it left no role for juries in 50 disparate state

tort regimes to second-guess the safety of a vaccine's approved design. Inconsistent determinations of the "safest" vaccine design by courts in different states would undermine the NVP Agencies' central role in combating the spread of infectious diseases. As this Court recognized just last Term, "[s]tate tort law that requires a manufacturer's [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." *Riegel*, 128 S. Ct. at 1008. For reasons discussed above, this admonition is even truer for vaccines.

With the comprehensive and integrated program created by the Vaccine Act, Congress averted the public health crisis in 1986. This Court should grant this petition to review an opinion that invites the public health crisis back.

CONCLUSION

For the foregoing reasons, this Court should grant a writ of certiorari to review the judgment of the Supreme Court of Georgia.

Respectfully submitted.

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APPENDICES

APPENDIX A

SUPREME COURT OF GEORGIA

AMERICAN HOME PRODUCTS CORPORATION et al.
v.
FERRARI et al.

No. S07G1708.

Oct. 6, 2008.

CARLEY, Justice.

Appellees Marcelo and Carolyn Ferrari, individually and on behalf of their minor son, brought suit against several vaccine manufacturers, including Appellants, alleging that their son suffered neurological damage caused by vaccines made with the preservative thimerosal, which contained the toxic substance mercury. Appellees' claims under Georgia law included strict liability and negligence. They specifically alleged that Appellants could and should have manufactured children's vaccines without thimerosal before Appellees' son was vaccinated in 1998.

The trial court granted partial summary judgment in favor of Appellants, ruling that Appellees' design defect claims were preempted by the National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. § 300aa-1 et seq. (Vaccine Act). Section 300aa-22 (b)(1) of the Vaccine Act reads as follows:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

On appeal, the Court of Appeals summarized the parties' arguments as follows:

> [Appellants] argue that the Vaccine Act bars [Appellees'] design defect claims because "any vaccine-related injury would be deemed 'unavoidable' if the vaccine was properly prepared and accompanied by proper warnings." [Cit.] [Appellants] essentially equate FDA [Food and Drug Administration] approval with a determination that side effects are "unavoidable." [Cit.] [Appellees], on the other hand, assert that design defect claims are barred only if the side effects are determined on a case-by-case basis to be "unavoidable." They argue that their child's injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines or if they had simply manufactured single-dose vials that did not require a preservative.

Ferrari v. American Home Products Corp., 286 Ga. App. 305, 308, 650 S.E.2d 585 (2007). The Court of

Appeals determined that two alternative readings of 42 U.S.C. § 300aa-22 (b)(1) exist:

> One reading is that vaccine injuries are "unavoidable" and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis.

Ferrari v. American Home Products Corp., supra at 311, 650 S.E.2d 585. The Court of Appeals held that, despite clear legislative history favoring the first reading, *Bates v. Dow Agrosciences*, 544 U.S. 431, 449(III), 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005) imposes

> "a duty to accept the reading (of the Vaccine Act) that disfavors pre-emption," and we cannot resort to an examination of legislative history to discern Congress's intent. [Cit.] Because two plausible, alternative readings of the Vaccine Act exist, we must conclude that the trial court erred by finding that [Appellees'] design defect claims are preempted.

Ferrari v. American Home Products Corp., supra at 312(1), 650 S.E.2d 585. We granted certiorari to consider this ruling. Although the Court of Appeals erred in holding that *Bates* precludes the use of legislative history, we nevertheless affirm the judgment of the Court of Appeals because a full

examination of both the text of 42 U.S.C. § 300aa-22 (b)(1) and the congressional intent behind it shows that the Vaccine Act does not preempt all design defect claims, but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable.

1. "Except as provided in subsections (b), (c), and (e) [of § 300aa-22] State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22 (a). Thus, in construing subsection (b)(1), "we are presented with the task of interpreting a statutory provision that expressly pre-empts state law." *Medtronic v. Lohr*, 518 U.S. 470, 484(III), 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996). Although this subsection "preempts state law to the extent stated, the [Vaccine] Act, by expressly reserving state courts a role with respect to claims made under the Act, does not preclude state courts from adjudicating issues raised regarding it ([cit.])." *Militrano v. Lederle Laboratories*, 3 Misc. 3d 523, 769 N.Y.S.2d 839, 843 (2003), aff'd, 26 A.D.3d 475, 810 N.Y.S.2d 506 (App. Div. 2006).

While the language of subsection (b)(1) indicates that Congress intended to preempt some state law, we are nonetheless required to

> "identify the domain expressly pre empted" by that language, [cit.] Although our analysis of the scope of the pre-emption statute must begin with its text, [cit.], our

interpretation of that language does not occur in a contextual vacuum. Rather, that interpretation is informed by two presumptions about the nature of pre-emption. [Cit.] First, because the States are independent sovereigns in our federal system, . . . Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has "legislated . . . in a field which the States have traditionally occupied," [cit.], we "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." [Cits.] . . . [T]his assumption should apply . . . to questions concerning the *scope* of its intended invalidation of state law, [cit.] . . . That approach is consistent with both federalism concerns and the historic primacy of state regulation of matters of health and safety. Second, our analysis of the scope of the statute's pre-emption is guided by [the] oft-repeated comment . . . that "(t)he purpose of Congress is the ultimate touchstone" in every pre-emption case. [Cits.] As a result, any understanding of the scope of a pre-emption statute must rest primarily on "a fair understanding of *congressional purpose*." [Cit.] Congress' intent, of course, primarily is discerned from the language of the pre-emption statute and the "statutory framework" surrounding it.

> [Cit.] Also relevant, however, is the "structure and purpose of the statute as a whole," [cit.], as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law. (Emphasis in original.)

Medtronic v. Lohr, supra at 484-486(III), 116 S. Ct. 2240 (with five Justices joining this part of the Supreme Court's opinion).

The Court of Appeals viewed *Bates* as having drastically changed this traditional preemption analysis, so as to make the presumption against preemption irrebuttable and to require examination of the statutory language alone. *Ferrari v. American Home Products Corp.*, supra at 310, 650 S.E.2d 585. "However, *Bates* does not require a court to automatically accept a plausible interpretation of a statute which disfavors preemption." *Bruesewitz v. Wyeth*, 508 F. Supp. 2d 430, 444(V)(B)(2)(a) (E.D. Pa. 2007). *Bates* quotes from the above-quoted portion of *Medtronic* which sets forth the presumption against preemption, without any indication of disapproval. Furthermore, "*Bates* itself relies on the congressional intent behind [the statute before it] when applying the rule [disfavoring preemption]. [Cit.]" *Bruesewitz v. Wyeth*, supra. See also *Bates v. Dow Agrosciences*, supra at 452(III), fn. 26, 125 S. Ct. 1788 (examining legislative history).

It therefore appears that the Court of Appeals took "one part of the *Bates* ruling out of its context, and [gave] it broader scope than is appropriate." *Bruesewitz v. Wyeth*, supra. Nevertheless, a majority of seven Justices in *Bates* "gave the most explicit statement yet of the presumption against preemption in a product preemption case" and "fully demonstrated its commitment to the presumption against preemption except in the narrowest of circumstances." J. Eggen, "The Normalization of Product Preemption Doctrine," 57 Ala. L. Rev. 725, 762-763(III)(B) (2006).

2. Only two federal district courts and one state other than Georgia have considered in published opinions whether 42 U.S.C. § 300aa-22 (b)(1) preempts all claims that a vaccine was defectively designed. *Bruesewitz v. Wyeth*, supra; *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297(V)(B) (E.D. Pa. 2007) (same court as *Bruesewitz*); *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659, 662(II)(B) (S.D. Tex. 2004); *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 843-846, aff'd, 810 N.Y.S.2d, supra at 508. Each of these cases held that all such claims are preempted. However, every case correctly recognized that Congress modeled subsection (b)(1) after comment k to § 402A of the Restatement (Second) of Torts. "Section 402A is a general section providing for strict products liability." *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 844. Comment k excepts from strict liability the seller of

> [u]navoidably unsafe products. There are some products which, in the present state of

> human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many . . . drugs, vaccines, and the like . . . .

Restatement (Second) of Torts § 402A cmt. k. The phrase "properly prepared, and accompanied by proper directions and warning" refers to an absence of manufacturing or warning defects and, thus, comment k distinguishes the three fundamental types of products liability: defects in design, manufacturing, and packaging or marketing. *Sykes v. Glaxo-SmithKline*, supra at 300(V)(B)(3); *Blackmon v. American Home Products Corp.*, supra at 664(II)(B). See also *Banks v. ICI Americas*, 264 Ga. 732, 733(1), 450 S.E.2d 671 (1994) ("There are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects. [Cit.]").

However, both *Sykes* and *Blackmon* erroneously construed comment k to support its interpretation of 42 U.S.C. § 300aa-22 (b)(1) as rejecting a case-by-case determination of whether a certain side effect was unavoidable. In particular, *Sykes v. Glaxo-SmithKline*, supra at 302(V)(B)(4), mistakenly held that such interpretation "mirrors this established area of tort law for unavoidably unsafe products" as set forth in comment k. "Comment k., however, has been interpreted in a variety of ways . . ., and there

has been a wide range of disagreement regarding its application." *Freeman v. Hoffman-La Roche*, 260 Neb. 552, 618 N.W.2d 827, 835(IV)(1)(a)(ii) (2000). Only a few jurisdictions have held that any prescription drug is deemed unavoidably unsafe and, thus, that strict liability for defective design is barred. *Freeman v. Hoffman-La Roche*, supra at 836(IV)(1)(a)(ii); *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d, supra at 846. Most of the states, including Georgia, "that have adopted Comment k have applied it in a more limited fashion and on a case-by-case basis. [Cits.]" *Bryant v. Hoffmann-La Roche*, 262 Ga. App. 401, 404(2), 585 S.E.2d 723 (2003) (physical precedent, with one judge urging adoption of a design defect test in the Restatement (Third) of Torts, which test was neither adopted by Congress in the Vaccine Act nor in existence at the time). Indeed, even *Bruesewitz* understands comment k in this manner:

> Comment k, therefore, suggests that the question of whether a particular vaccine is unavoidably unsafe-and therefore subject to the immunity from suit posited by comment k-is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

Bruesewitz v. Wyeth, supra at 445(V)(B)(3). Thus, the court in *Bruesewitz*, despite its adherence to *Sykes* "ultimate holding, was compelled to acknowledge *Sykes*" misunderstanding of comment k. *Bruesewitz v. Wyeth*, supra at 445-446(V)(B)(3)

("conclud[ing] that § 22(b) is broader than comment k").

3. An analysis of the language and intent of 42 U.S.C. § 300aa-22 (b)(1), unhindered by the mistakes of *Blackmon* and *Sykes*, shows that Congress not only adopted comment k, but understood that comment in the same way that *Bruesewitz* and the great majority of other courts came to understand it. Subsection (b)(1) borrows liberally from the language of comment k, and the committee report on which *Blackmon*, *Sykes*, *Bruesewitz*, and *Militrano* rely states, without qualification, that "[t]his provision sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) . . . ." H.R. Rep. 99-908, at 25 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6366.

The text of subsection (b)(1) is most consistent with the majority understanding of comment k. Under that subsection, a vaccine manufacturer is not civilly liable "if the [vaccine-related] injury or death resulted from side effects that were unavoidable . . . ." The conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable. In order to bar all liability for defective design and to permit liability only for manufacturing and warning defects, Congress could easily have omitted this clause, retained the last clause, and made the bar to civil liability conditional on proper preparation and warnings, so that subsection (b)(1) would simply state that a vaccine manufacturer is not civilly liable "if the vaccine was properly prepared and was

accompanied by proper directions and warnings." Thus, Appellants effectively "favor reading . . . words out of the statute. . . . This amputated version . . . would no doubt have clearly and succinctly commanded the pre-emption of *all* state" tort claims for defective design. (Emphasis in original.) *Bates v. Dow Agrosciences*, supra at 448-449(III), 125 S. Ct. 1788.

As the statute is actually written, however, it is best understood as barring liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging. Conversely, if such effects were avoidable by a feasible alternative design, liability is not completely barred. Accordingly, the last clause of subsection (b)(1) was necessary to ensure that its bar to liability would not apply to the manufacturing and packaging process, but only to side effects which were not avoidable by a safer design.

4. This construction of 42 U.S.C. § 300aa-22 (b)(1) is bolstered by the previously cited 1986 committee report in the following explanation:

> The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. *Militrano v. Lederle Laboratories*, 810 N.Y.S.2d, supra, acknowledges that this wording "appears to leave open the possibility of a design defect claim with respect [to] vaccines covered by the Vaccine Act. . . ." Indeed, that language alone refutes the Court of Appeals' concession that there is "clear legislative history to the contrary. . . ." *Ferrari v. American Home Products Corp.*, supra at 312(1), 650 S.E.2d 585. Subsequent language in the 1986 committee report carries a similar implication, when it recognizes that the Vaccine Act established a "no-fault compensation system," providing an award to vaccine-injured persons "even if the manufacturer has made as safe a vaccine as possible." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367.

This context must be considered when reading the following sentence on which *Blackmon, Sykes, Bruesewitz, Militrano*, and Appellants rely:

> Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. This sentence includes both those persons who have been injured by vaccines which were as safely designed as possible and those injured by vaccines for which there was a safer feasible alternative design. Accordingly, the committee report does not

use language which indicates that use of the compensation system is mandatory. The immediately preceding sentence states that "[v]accine-injured persons will now have an appealing alternative to the tort system." H.R. Rep. 99-908, at 26, 1986 U.S.C.C.A.N. at 6367. Thus, Congress defended the new compensation system by assuming that it would attract even vaccine-injured persons who may be able to prove that the vaccine was not made as safe as reasonably possible. Such an assumption about a no-fault compensation system is certainly questionable, to say the least. However, the assumption is not relevant for its accuracy, but rather for its illumination of congressional intent. Upon considering Congress' assumption regarding the compensation system for that proper purpose, we conclude that the sentence of the committee report on which Appellants rely means only that, in the committee's opinion, if a vaccine-injured person does not have a claim for a manufacturing or warning defect, he should find the compensation system appealing even though he is authorized to attempt to prove the existence of a safer design in the tort system. Accordingly, that sentence does not mean that 42 U.S.C. § 300aa-22 (b)(1) preempts all design defect claims.

The Court of Appeals rejected the use of "subsequent legislative history" as "'a hazardous basis for inferring the intent of an earlier Congress.' [Cit.]" *Ferrari v. American Home Products Corp.*, supra at 311, fn. 9, 650 S.E.2d 585. That subsequent legislative history consists of a report by the same committee which originally considered the Vaccine Act and which produced the 1986 report relied upon

by Appellants and the courts. The subsequent committee report was issued in 1987, the year following passage of the Vaccine Act, and related to amendments to that Act which did become law. In these circumstances, the 1987 committee report is relevant to "shed[ ] light on allegedly ambiguous language" and "certainly constitutes a prophylactic against adopting a tortured reading of an otherwise plain statute." *Grapevine Imports v. United States*, 71 Fed. Cl. 324, 335(II)(C)(3) (2006). That report is strikingly clear and emphatic:

> [T]he codification of Comment (k) of The Restatement (Second) of Torts was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.

H.R. Rep. 100-391(I), at 691 (1987), as reprinted in 1987 U.S.C.C.A.N. 2313-1, 2313-365.

Furthermore, an amendment to the Vaccine Act which would have established "that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act." H.R. Rep. 100-391(I), at 691, 1987 U.S.C.C.A.N. at 2313-365. "Generally the rejection of an amendment indicates that the legislature does not intend the bill to

include the provisions embodied in the rejected amendment. [Cits.]" 2A Sutherland Statutory Construction § 48:18 (7th ed.).

5. Our analysis is consistent with the structure and purpose of the Vaccine Act as a whole, as correctly summarized by the Court of Appeals:

> Congress enacted the Vaccine Act "to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensat(ing) victims of vaccine-related injuries quickly." [Cit.] The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries and requires injured parties to file a petition in the vaccine court. [Cits.] If the injured party is not satisfied with the outcome of the vaccine court process, he or she may pursue a traditional tort action, subject to certain restrictions imposed by the Vaccine Act. [Cits.]

Ferrari v. American Home Products Corp., supra at 306, 650 S.E.2d 585. Accordingly, we must not "overstate the degree of uniformity and centralization that characterizes" the Vaccine Act. *Bates v. Dow Agrosciences*, supra at 450(III), 125 S. Ct. 1788. Having thoroughly examined both the text of 42 U.S.C. § 300aa-22 (b)(1) and the congressional intent behind that subsection and the entire Act, including the relevant legislative history, we hold that subsection (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers,

but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe.

Even if the language of 42 U.S.C. § 300aa-22 (b)(1) is ambiguous, the legislative history hardly shows a "clear and manifest" congressional purpose to supplant state tort law with respect to claims of defective design. Thus, although the Court of Appeals mistakenly construed *Bates* to preclude reliance on any indication of congressional intent other than the statutory language, *Bates* would nonetheless apply to resolve any ambiguity in subsection (b)(1) against preemption.

> Even if [Appellants] had offered us a plausible alternative reading of [that subsection]-indeed, even if its alternative were just as plausible as our reading of that text-we would nevertheless have a duty to accept the reading that disfavors pre-emption. . . . The long history of tort litigation against manufacturers of [prescription drugs and vaccines] adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly. [Cit.]

Bates v. Dow Agrosciences, supra at 449(III), 125 S. Ct. 1788.

Our holding is not undermined by the "four conclusions" of *Sykes v. Glaxo-SmithKline*, supra at 301-303(V)(B)(4), as utilized in *Bruesewitz v. Wyeth*, supra at 445(V)(B)(3). First, 42 U.S.C. § 300aa-22 (b)(1) does not "protect vaccine manufacturers from suit [for] design defects." *Bruesewitz v. Wyeth*, supra. Rather, it protects them from liability for unavoidable side effects. Second, the federal district court in *Bruesewitz* and *Sykes* failed to explain how the National Vaccine Program set up by the Vaccine Act will better promote the discovery of safer alternative designs if manufacturers are given a blanket tort immunity for design defects. See *Bates v. Dow Agrosciences*, supra at 450(III), 125 S. Ct. 1788; *Militrano v. Lederle Laboratories*, 769 N.Y.S.2d 839 supra (decisions favoring the majority view of comment k "emphasize that blanket immunity from tort liability would remove an incentive for developing safer designs ([cit.])"). Third, as discussed above, the legislative history does not show that Congress intended that the no-fault compensation system would balance the supposed elimination of design defect claims. Fourth, the district court did not cite any authority for its conclusion that FDA approval alone renders a vaccine unavoidably unsafe, and that conclusion is not compatible with the majority interpretation of comment k in the realm of prescription drugs. See *Adams v. G.D. Searle & Co.*, 576 So.2d 728, 733 (Fla. App. 1991) (cited in *Bryant v. Hoffman-La Roche*, supra) ("it seems likely to us that a drug manufacturer is in a better position to monitor the current state of knowledge and technology, as applied to its products, than is the FDA. We

hesitate to hold that a manufacturer is excused from making changes it knows will improve its product merely because an older, more dangerous version received FDA approval. We therefore reject a blanket approach and decline to apply comment k to all prescription products."); Christopher J. Albee & Dawn Kilgallen, Comment, *Providing Blanket Comment K Immunity to All FDA Approved Ethical Drugs: The Defect in Grundberg v. Upjohn Co.*, 7 St. John's J. Legal Comment 475 (1991).

The text of 42 U.S.C. § 300aa-22 (b)(1) is not directed towards any particular cause of action, but rather encompasses products liability claims based upon strict liability as well as negligence. *Bruesewitz v. Wyeth*, supra at 440(V)(B), fn. 4; *Sykes v. Glaxo-SmithKline*, supra at 303(V)(B)(5); *Blackmon v. American Home Products Corp.*, supra at 666(II)(B). Therefore, although the Vaccine Act provides for limited no-fault compensation, construing subsection (b)(1) as set forth in *Bruesewitz*, *Sykes*, *Blackmon*, and *Militrano* "would 'have the perverse effect of granting complete [tort] immunity from design defect liability to an entire industry . . . .' [Cit.]" *Doyle v. Volkswagenwerk Aktiengesellschaft*, 267 Ga. 574, 576-577, 481 S.E.2d 518 (1997) (quoting *Medtronic v. Lohr*, supra at 487(IV), 116 S. Ct. 2240). In the absence of any clear and manifest congressional purpose to achieve that result, we must reject such a far-reaching interpretation of 42 U.S.C. § 300aa-22 (b)(1), at least until the Supreme Court of the United States has spoken on the issue.

Judgment affirmed. All the Justices concur.

APPENDIX B

COURT OF APPEALS OF GEORGIA, FOURTH DIVISION

FERRARI et al. v. AMERICAN HOME PRODUCTS CORPORATION et al.	No. A07A0306.

July 5, 2007.

SMITH, Presiding Judge.

In this case involving an issue of first impression, we are called upon to address whether the National Childhood Vaccine Injury Compensation Act of 1986 ("Vaccine Act"), 42 U.S.C. § 300aa-1 et seq., preempts a lawsuit for injuries allegedly caused by the routine vaccination of a child.[1] The trial court concluded that a portion of the plaintiffs' claims are preempted by the Vaccine Act and granted partial summary judgment in favor of the defendants. For the reasons set forth below, we reverse.

Summary judgment is proper when no genuine issue of material fact appears and the movant is entitled to judgment as a matter of law. OCGA § 9-11-56(c). We review the grant or denial of a motion for summary judgment de novo, construing the evidence and all reasonable inferences in the light

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[1] This appeal does not address the causation element of the plaintiffs' claims.

most favorable to the nonmovant. *Matjoulis v. Integon Gen. Ins. Corp.*, 226 Ga. App. 459(1), 486 S.E.2d 684 (1997). So viewed, the record shows that Marcelo and Carolyn Ferrari, individually and on behalf of their minor son, Stefan Ferrari, sued nine children's vaccine manufacturers ("vaccine defendants"),[2] eight thimerosal manufacturers,[3] and one rhogam manufacturer[4] for alleged neurological damage to their son caused by vaccines containing thimerosal preservative, which in turn contained mercury. According to the Ferraris, their son's neurological damage was caused by the mercury, which is toxic to humans. The Ferraris also sued Georgia Power, claiming that mercury emissions from its power plants also injured their son. The Ferraris asserted claims under Georgia law for strict liability and negligence. The Ferraris alleged the vaccine defendants negligently researched, manufactured, tested or failed to test, warned or failed to warn, and failed to recall thimerosal-containing vaccines. According to the Ferraris, the vaccine defendants could and should have manufactured children's vaccines without thimerosal before their son was vaccinated in 1998.

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[2] Sanofi Pasteur, Inc., Aventis Pharmaceuticals, Inc., SmithKline Beecham Corporation, GlaxoSmithKline, GlaxoSmithKline Biologicals, S.A., GlaxoSmithKline Belgium, Wyeth, Lederle, Inc., and Lederle Pharmaceutical.

[3] Eli Lilly and Company, Inc., Sigma-Aldrich, Inc., Sigma-Aldrich Corporation, Spectrum Laboratory Products, Inc., Meridian Chemical and Equipment, Inc., American International Chemical, Inc., Dolder, Ltd., and Uriach Corporation.

[4] Ortho-Clinical Diagnostics.

SmithKline Beecham Corporation, GlaxoSmithKline Biologicals, S.A., and Wyeth filed answers denying liability and moved for summary judgment in their favor, claiming that the Vaccine Act preempted the Ferraris' claims. The trial court found that the preemption doctrine applied and granted partial summary judgment to the vaccine defendants on the Ferraris' design defect claims, their failure-to-warn claims to the extent that they alleged a failure to warn the plaintiffs or the general public, and their breach of warranty claims to the extent they asserted that the vaccines were defectively designed. On appeal, the Ferraris assert that the trial court erred by: (1) finding that its design defect claims are preempted; and (2) refusing to consider constitutional arguments raised by the Ferraris after the court had orally announced its ruling in favor of the vaccine defendants.

THE VACCINE ACT

In 1986, Congress enacted the Vaccine Act "to prevent manufacturers from leaving vaccine production or significantly increasing their prices, while at the same time compensat[ing] victims of vaccine-related injuries quickly." *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007). The Vaccine Act creates a no-fault compensation system for victims of certain vaccine-related injuries and requires injured parties to file a petition in the vaccine court. Id. at 299-300; see also 42 U.S.C. §§ 300aa-11(a)(2)(A), 300aa-13(a)(1)(A, B). If the injured party is not satisfied with the outcome of the Vaccine Court process, he or she may pursue a traditional tort action, subject to certain restrictions

imposed by the vaccine act. *Sykes*, 484 F. Supp. 2d at 300-301; see also 42 U.S.C. § 300aa-21(a)(1)-(2). These restrictions modify state law as follows:

> (a) General rule. Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
>
> (b) Unavoidable adverse side effects; warnings.
>
> (1) *No vaccine manufacturer shall be liable in a civil action* for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] *if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*
>
> (2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.S. §§ 301 et seq.] and section 351 of the Public Health Service Act [42 U.S.C.S. § 262] (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury

or death for which the civil action was brought unless the plaintiff shows-

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 2123(d)(2) [42 U.S.C.S. § 300aa-23(d)(2)(A) or (B)], or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings. No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after the effective date of this part [effective Oct. 1, 1988] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction. The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil

> action against such manufacturer for such injury or death.
>
> (e) *Preemption. No State may establish or enforce a law which prohibits an individual from bringing a* civil *action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle [42 U.S.C.S. § § 300aa-10 et seq.].*

(Emphasis supplied.) 42 U.S.C. § 300aa-22. The Vaccine Act also limits the recovery of punitive damages to cases in which

> the manufacturer engaged in . . . (A) fraud or intentional and wrongful withholding of information from the [FDA] during any phase of a proceeding for approval of [a] vaccine . . ., (B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or (C) other criminal or illegal activity relating to the safety and effectiveness of vaccines, which activity related to the vaccine-related injury or death for which the civil action was brought.

42 U.S.C. § 300aa-23 (d)(2).

These restrictions expressly "convey Congress's intent to supersede, or preempt, state tort law standards and create legal protections that apply in any civil action brought against a vaccine manufacturer." *Skyes*, supra, 484 F. Supp. 2d at

297. As in *Sykes*, the vaccine defendants argue that the Vaccine Act bars the Ferraris' design defect claims because "any vaccine-related injury would be deemed 'unavoidable' if the vaccine was properly prepared and accompanied by proper warnings." Id. at 299. The vaccine defendants essentially equate FDA approval with a determination that side effects are "unavoidable." See id.

The Ferraris, on the other hand, assert that design defect claims are barred only if the side effects are determined on a case-by-case basis to be "unavoidable." They argue that their child's injuries could have been avoided if the defendants had used a mercury-free preservative for multi-dose vials of their vaccines or if they had simply manufactured single-dose vials that did not require a preservative.

JUDICIAL INTERPRETATION OF SCOPE OF VACCINE ACT PREEMPTION

Only a handful of courts have addressed the scope of the preemption clause found in 42 U.S.C. § 300aa-22, and each has concluded, after examining the legislative history of the Vaccine Act, that the issue of whether side effects are "unavoidable" cannot be litigated in civil actions. See *Sykes*, supra, 484 F. Supp. 2d at 307-308; *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004); *Militrano v. Lederle Laboratories*, 3 Misc. 3d 523, 769 N.Y.S.2d 839 (2003), aff'd, 26 A.D.3d 475, 810 N.Y.S.2d 506 (2006). Each of these cases, however, was either decided before or fails to

address the Supreme Court's landmark opinion[5] in *Bates v. Dow AgroSciences*, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), on traditional preemption analysis. The Ferraris assert that application of the reasoning in *Bates*, supra, mandates a different outcome. We agree.

BATES

In *Bates*, the Supreme Court "overturn[ed] thirteen years of precedent during which pesticide companies enjoyed relative immunity from tort liability." Joseph Frueh, Pesticides, Preemption, and the Return of Tort Protection, 23 Yale J. on Reg. 299, 300 (Summer 2006). Before *Bates*, courts interpreted the following language from the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA")[6] to bar tort claims: "State[s] shall not impose or continue in effect any requirement for labeling or packaging in addition to or different from those required under [FIFRA]." 7 U.S.C. § 136v(b). *Bates*, supra, 544 U.S. at 436, nn. 4, 5, 125 S. Ct.

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[5] See Joseph Frueh, Pesticides, Preemption, and the Return of Tort Protection, 23 Yale J. on Reg. 299, 309(V) (Summer 2006) ("*Bates* urges that courts must stay the hand of preemption unless given a nearly explicit mandate by the enabling statute."); Kim Ly, *Bates v. Dow AgroSciences:* Overcoming Federal Preemption and Giving the People a Voice, 26 J. Nat. Assn. Admin. L. Judges 297, 336(VI) (Spring 2006) ("the *Bates* Court has signaled a shift away and against federal preemption of common law tort [claims]"); Christene Beaupre, Case Comment: Product Safety-Food and Drug Laws: How Bates Changed the Face of Preemption, 82 N. Dak. L. Rev. 579, 601(IV)(A) (2006) ("The *Bates* decision may reverse . . . the trend to uphold preemption claims and bar state law claims.") (citation and footnote omitted).

[6] 7 U.S.C. § 136 et seq.

1788. According to this view, judgments in civil actions might compel pesticide companies to change their labels and would therefore violate the prohibition contained in § 136v(b). See id. at 443, 125 S. Ct. 1788.

The Supreme Court rejected this approach, and adopted a "parallel requirements reading" of the phrase "in addition to or different from" in FIFRA to allow civil suits based upon common law standards of conduct that served FIFRA's primary purpose of preventing false or misleading statements or inadequate instructions or warnings. *Bates*, supra, at 447-448, 125 S. Ct. 1788. In so holding, the Supreme Court noted that:

> Conspicuously absent from the submissions by Dow and the United States is any plausible alternative interpretation of "in addition to or different from" that would give that phrase meaning. . . . Even if Dow had offered us a plausible alternative reading of § 136v(b)-indeed, even if its alternative were just as plausible as our reading of that text-*we would nevertheless have a duty to accept the reading that disfavors pre-emption.* "Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." [Cit.] "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest." [Cits.]

(Punctuation omitted; emphasis supplied.) Id. at 448-449(III), 125 S. Ct. 1788. The emphasized language above drastically changes traditional preemption analysis.

Before *Bates*, application of a presumption against preemption to questions concerning the scope of an express preemption clause was controversial. See, e.g., *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996); *Cipollone v. Liggett Group*, 505 U.S. 504, 545-546, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992) (Scalia, J., concurring in the judgment in part and dissenting in part). Furthermore, the presumption against preemption was rebuttable,[7] and courts examined legislative history to determine Congress's intent with regard to ambiguous language in express preemption clauses.[8]

The pivotal language in *Bates* changed traditional preemption analysis in two ways: (1) There is no longer a rebuttable *presumption* against preemption, but a *duty to accept* the reading of an express preemption statute that disfavors preemption; and (2) preemption analysis ends with an examination of the statutory language alone. Under this approach, it appears that legislative history should no longer be examined to discern Congressional intent when an express preemption clause has two plausible alternative readings.

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[7] See, e.g., *Patrick Fur Farm v. United Vaccines*, 286 Wis.2d 774, 780, n. 2, 703 N.W.2d 707 (Wis. App. 2005).

[8] See, e.g., *Sykes*, supra, 484 F. Supp. 2d at 304.

Since *Bates*, one court has adopted these changes into its preemption analysis. See *Blue Flame Energy Corp.*, 171 Ohio App.3d 514, 534, 871 N.E.2d 1227 (2006) ("[I]f the express preemption provision is ambiguous, a court has a duty to accept the reading that disfavors pre-emption, particularly in areas of traditional state regulation.") (citations omitted). While adopting these changes, however, the Ohio Court of Appeals did not apply them, because it concluded that the express preemption clause before it was unambiguous. Id. at 532, 871 N.E.2d 1227. Therefore, if we conclude that the Vaccine Act's preemption clause is subject to two alternative readings, this court may be the first to apply the changes created by *Bates*.

APPLICATION OF *BATES* TO THE VACCINE ACT

The statutory language at issue provides: "No vaccine manufacturer shall be liable in a civil action . . . if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1). Two of the courts addressing this language have concluded that two alternative, plausible readings exist with regard to preemption of the issue of unavoidable side effects, and we agree with their conclusion. *Sykes*, supra, 484 F. Supp. 2d at 304; *Militrano*, supra, 769 N.Y.S.2d at 843-844. One reading is that vaccine injuries are "unavoidable" and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings. The other reading is that

design defect claims are preempted only if the side effects are determined to be unavoidable on a case-by-case basis.

We also agree with our fellow courts' conclusion that when the contemporaneous legislative history of the Vaccine Act is examined, Congress's intent to preempt this issue becomes clear.[9] *Skyes*, supra, 484 F. Supp. 2d at 308-309; *Militrano*, supra, 769 N.Y.S.2d at 843-844. A passage in the Report of the Committee on Energy and Commerce states:

> Given the existence of the compensation system in the Vaccine Act, ... [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings they should pursue recompense in the compensation system, not the tort system.

(Punctuation omitted.) *Sykes*, supra, 484 F. Supp. 2d at 300. See also *Militrano*, supra, 810 N.Y.S.2d at 508; *Blackmon*, supra, 328 F. Supp. 2d at 664-665.

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[9] The Ferraris point to subsequent legislative history accompanying an amendment to fund the Vaccine Act as evidence of a contrary intent. However, "subsequent legislative history is a hazardous basis for inferring the intent of an earlier Congress." (Citation and punctuation omitted.) *Pension Benefit Guaranty Corp. v. LTV Corp.*, 496 U.S. 633, 650(III)(B), 110 S. Ct. 2668, 110 L. Ed. 2d 579 (1990).

1. Because two alternative readings of the Vaccine Act exist, application of the Supreme Court's pronouncement in *Bates*, supra, is outcome determinative.[10] Under *Bates*, we "have a duty to accept the reading [of the Vaccine Act] that disfavors pre-emption," and we cannot resort to an examination of legislative history to discern Congress's intent. 544 U.S. at 449(III), 125 S. Ct. 1788. Because two plausible, alternative readings of the Vaccine Act exist, we must conclude that the trial court erred by finding that the Ferraris' design defect claims are preempted.

While this result differs from that reached by other courts addressing the preemptive effect of the Vaccine Act, none of those courts addressed the impact of *Bates* on the analysis of ambiguous express preemption clauses. We recognize that this result is anomalous given the clear legislative history to the contrary, but we are constrained to follow the Supreme Court's explicit guidance in *Bates*. While the vaccine defendants urge us to limit the Supreme Court's pronouncement in *Bates* to the facts of the case before it, there is no rational basis for us to do so. The language at issue is very broad and addresses preemption analysis generally.

2. Our holding in Division 1 renders moot the Ferraris' remaining enumeration of error regarding

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[10] The vaccine defendants assert that *Bates* should be limited to its facts and apply only in cases involving the same or similar preemption statutes. We find no merit in the argument. The language used by the Supreme Court in *Bates* is very broad and applies to the analysis of any express preemption statute.

the trial court's refusal to consider their constitutional claims.

Judgment reversed.

BARNES, C.J., and MILLER, J., concur.

APPENDIX C

IN THE STATE COURT OF FULTON COUNTY, STATE OF GEORGIA

MARCELO A. FERRARI and CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Plaintiffs,

v.

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH; WYETH LABORATORIES; WYETH-AYERST; WYETH-AYERST LABORATORIES; WYETH LEDERLE; WYETHER LEDERLE; WYETHER LEDERLE VACCINES AND LEDERLE LABORATORIES; ORTHO-CLINICAL DIAGNOSTICS, INC.; SMITHKLINE BEECHAM CORPORATION; GEORGIA POWER COMPANY; and JOHN DOES 1-20 who are individuals, proprietorships, corporations or other entities whose names and identities are otherwise unknown to the plaintiffs

Defendants.

CIVIL ACTION FILE
NO. 02 VS 031404-F.

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, AND GLAXOSMITHKLINE BIOLOGICALS S.A.'S MOTION FOR SUMMARY JUDGMENT, OR ALTERNATIVELY, MOTION TO DISMISS OR REQUIRE REPLEADING OF ALLEGATIONS

Plaintiffs allege in this product liability action that the minor plaintiff suffers from a neurological condition that was caused, in part, by exposure to FDA-approved vaccines containing the preservative thimerosal. Before the Court is a Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations filed by Defendants WYETH (f/k/a AMERICAN HOME PRODUCTS CORPORATION), SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE and GLAXOSMITHKLINE BIOLOGICALS S.A. (collectively the "Vaccine Defendants"). The Vaccine Defendants argue that the Court should grant summary judgment because the National Childhood Vaccine Injury Compensation Act, 42 U.S.C. § 300aa-1 *et seq.* (*hereinafter* the "Vaccine Act"), pre-empts all of Plaintiffs' claims. The Vaccine Defendants assert that all of Plaintiffs' claims, including failure to warn, are pre-empted by Section 22(b) of the Vaccine Act because the claims are all based on a singular

design defect allegation, *i.e.*, that the FDA-approved vaccines at issue should not have contained the preservative thimerosal. The Vaccine Defendants also contend that Section 22(c) of the Vaccine Act bars Plaintiffs' claims for failure to warn Plaintiffs and the general public. The Vaccine Defendants additionally seek dismissal of Plaintiffs' fraud-based allegations pursuant to O.C.G.A. §§ 9-11-9(b) and 9-11-12 for failure to plead such allegations with particularity.

In support of their Motion, the Vaccine Defendants filed a memorandum, a statement of material facts and theories of recovery, the affidavit of Karen Raby Monson with attached exhibits A-H, and a reply memorandum in further support of their Motion. Plaintiffs filed a brief in opposition to the Motion and a response to the Vaccine Defendants' statement of material facts and theories of recovery. The Court has reviewed the papers submitted by each party, and on July 8, 2005, the Court heard oral argument on the Motion from counsel. At the conclusion of the argument, the Court ruled on the Vaccine Defendants' Motion. This Order reflects that ruling and the Court's supporting reasons. For the reasons that follow, the Vaccine Defendants' Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations is hereby **GRANTED IN PART** and **DENIED IN PART**.

BACKGROUND

On or about April 15, 2002, plaintiffs Marcelo and Carolyn Ferrari, individually and on behalf of the

minor plaintiff, Stefan R. Ferrari, commenced the instant proceeding by filing a complaint alleging that the minor plaintiff allegedly suffers from a neurological condition, which Plaintiffs claim was caused by exposure to FDA-approved vaccines containing the preservative thimerosal. Plaintiffs asserted claims under Georgia law for strict tort liability, negligence, fraud and deceit, negligent misrepresentation, and breach of warranty. Plaintiffs also sought punitive damages based upon assertions of gross negligence.

This Court dismissed without prejudice the claims of the minor plaintiff on January 6, 2003. On February 20, 2003, all discovery in this case was stayed until further order of the Court. On October 15, 2003, this Court dismissed without prejudice the claims alleged by the parent plaintiffs (other than their separate state law claims for loss of services and emotional distress). The dismissals afforded Plaintiffs the opportunity to file a petition in Vaccine Court. In October 2004, Plaintiffs, having filed a Vaccine Court petition, elected to terminate their proceeding in that forum and filed a Second Amended Complaint on October 25, 2004, asserting that they had "complied with all prerequisites under the National Vaccine Injury Compensation Act." The Court lifted the stay of proceedings on April 20, 2005.

The Vaccine Defendants filed the motion for summary judgment that is the subject of this Order on May 27, 2005, and filed a corrected Motion on

May 31, 2005.[1] Plaintiffs filed their brief in opposition on July 1, 2005, and the Vaccine Defendants filed a reply memorandum in further support of their Motion on July 7, 2005.

DISCUSSION

A. *The Vaccine Act*

Childhood vaccines play a central role in national health policy, and the Vaccine Act, which covers Plaintiffs' claims here, is integral to that policy. In 1986, the United States Congress passed the Vaccine Act, and created "a new system for compensating individuals who have been injured by vaccines routinely administered to children." H.R. Rep. 99-908, 99th Cong., 2d Sess. (1986), at 3, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6344. The Vaccine Act's legislative history documents the concerns that spurred enactment of the law. It notes the inability of the tort system to predictably and properly deal with claims on behalf of children alleging vaccine-related injuries, and that costly litigation without predictable results created an incentive for vaccine manufacturers to withdraw from making childhood vaccines critical to public health. *See id.* at 6344-48; *see also Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1116-17 (4th Cir. 1988) (Wilkins, J., concurring) ("As a . . . consequence of the increase in litigation, . . . manufacturers are reconsidering their

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[1] GlaxoSmithKline Biologicals s.a. ("Biologicals") did not appear in this action until it filed an answer with this Court on July 7,2005. At that time, Biologicals also filed a notice of joinder in the Vaccine Defendants' Motion.

future role in the vaccine market. The withdrawal of any manufacturer from the market poses a serious threat to public health, in the form of vaccine shortages with resulting decreased immunization and a possible resurgence of these diseases.").

The Vaccine Act reflects two specific policy goals of Congress. First, the federal legislative scheme aimed to simplify the procedure and the substantive rules of law applicable to vaccine-related injury claims, and so make it easier for injured parties to obtain compensation. To implement this policy, Congress established a special court ("Vaccine Court") as part of the United States Court of Federal Claims to adjudicate claims of "vaccine-related injury"[2] and to award compensation to injured individuals. *See Shalala v. Whitecotton*, 514 U.S. 268, 269 (1995) ("For injuries and deaths traceable to vaccinations, the [Vaccine] Act establishes a scheme of recovery designed to work faster and with greater ease than the civil tort system."). A claimant may recover by proving an injury plus causation. Proof that the vaccine at issue was negligently manufactured, defectively designed, or inadequately

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[2] "Vaccine-related injury" "means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine." 42 U.S.C. § 300aa-33(5). It includes claims alleging injury from thimerosal contained in FDA-approved vaccines. *See, e.g., Blackmon v. Am. Home Prods. Corp.*, 267 F. Supp. 2d 667, 673-75 (S.D. Tex. 2002); *Leroy v. Sec'y of HHS*, No. 02-392V, 2002 WL 31730680, at * 17 (Fed. Cl. Oct. 11, 2002); *Ashton v. Aventis Pasteur, Inc.*, 851 A.2d 908, 911-13 (Pa. Super. Ct. 2004).

labeled is not required to obtain compensation on any Vaccine Court petition. *See* 42 U.S.C. §§ 300aa-11(c)(1); 300aa-13(a)(1). Approximately 4,500 petitions seeking compensation based on allegations that thimerosal-containing vaccines and/or the Measles-Mumps-Rubella ("MMR") vaccine caused autism or autism spectrum disorder are currently pending before the Vaccine Court. *See In re Claims For Vaccine Injuries Resulting In Autism Spectrum Disorder Or A Similar Neurodevelopmental Disorder*, Autism Master File – Autism Update (Ct. Fed. Cl. June 27, 2005) (Hastings, S.M.).

Second, Congress intended to protect the supply of childhood vaccines in the United States by protecting vaccine manufacturers from the burden of costly litigation with unpredictable outcomes. The Vaccine Act protects vaccine manufacturers from costly civil litigation by: (i) barring civil actions such as this arising from vaccine-related injuries unless the claim was first presented in the Vaccine Court and the remedy exhausted[3]; (ii) immunizing vaccine manufacturers from liability for alleged vaccine-related injuries caused by vaccines that were properly prepared and accompanied by proper directions and warnings; and (iii) establishing legal presumptions as to the adequacy of vaccine warnings and against the imposition of punitive damages except in cases involving substantial wrongdoing.

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[3] Congress expected that a significant number of claims would be resolved in the Vaccine Court forum under the Vaccine Act's provisions for generous compensation. *See* 1986 U.S.C.C.A.N. at 6354.

See 42 U.S.C. §§ 300aa-11; 300aa-22; 300aa-23(d); *see also* 1986 U.S.C.C.A.N. at 6367. In addition to requiring that any vaccine-related injury claim be first presented in Vaccine Court, the Vaccine Act sets substantive and procedural rules that control the conduct of every civil action on claims of injury arising from post-October 1, 1988 vaccine administrations. Those limitations bar certain claims – including certain of the claims Plaintiffs assert in their Complaint – from being litigated in any civil action.

B. *The Vaccine Act's Express Pre-emption Of State Products Liability Law*

The Vaccine Defendants argue that Section 22 of the Vaccine Act pre-empts all state law design defect claims arising from vaccine-related injuries. Plaintiffs contend that the Vaccine Act merely supplements state products liability law, rather than displacing it. For the reasons set forth, the Court concludes that the Vaccine Act pre-empts all claims based on a theory of design defect.

Federal law may pre-empt state law in three ways:

> First, in enacting the federal law, Congress may explicitly define the extent to which it intends to preempt state law. (Citation omitted.) Second, even in the absence of express pre-emptive language, Congress may indicate an intent to occupy an entire field of regulation, in which case the states must leave all regulatory activity in that area to the Federal Government. (Citations

> omitted.) Finally, if Congress has not displaced state regulation entirely, it may nonetheless pre-empt state law to the extent that the state law actually conflicts with federal law.

Mich. Canners & Freezers Ass'n, Inc. v. Agric. Mktg. & Bargaining Bd., 467 U.S. 461, 469 (1984).

Section 22 of the Vaccine Act is an example of express pre-emption, as indicated by Section 22(a), which states that: "Except as provided in subsections [22](b), [22](c), and [22](e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).

Section 22(b)(1) of the Vaccine Act states:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1). That section states the express limitation on civil actions against vaccine manufacturers: it bars all civil actions arising from a vaccine-related injury if the injury could not have been avoided by proper preparation or proper labeling of the vaccine.

The cases Plaintiffs cite for the proposition that the Vaccine Act does not pre-empt state tort law are inapposite. The claims in those cases arose before the effective date of the Vaccine Act and concern vaccinations administered before October 1, 1988. The issue in those cases was whether state law claims had been impliedly pre-empted by federal law. Thus, the cases do not address whether Section 22 of the Vaccine Act expressly pre-empts design defect claims. *See Mazur v. Merck & Co., Inc.*, 742 F. Supp. 239, 246-47 (E.D. Pa. 1990); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108, 1113-14 (4th Cir. 1988); *Hurley v. Lederle Labs. Div. of American Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1989).

C. *Plaintiffs' Design Defect Claims*

With regard to Plaintiffs' design defect claims, the only issue before the Court is the extent of the pre-emptive effect of Section 22(b) of the Vaccine Act. Plaintiffs contend that Section 22(b)(1) simply codifies Comment k of Section 402A of the Restatement (Second) of Torts and directs states to determine under their tort law whether an alleged vaccine-related injury or death resulted from side effects that were unavoidable under any circumstances, including design standards that might be imposed by state tort law. Plaintiffs maintain that the Vaccine Act only bars their design defect claims here if the Court determines under Georgia products liability law that the side effects of the vaccines at issue are unavoidable.

Plaintiffs construe the statute as if it ended with the words "side effects that were unavoidable." The statute continues, however, that vaccine manufacturers are not subject to civil liability where the alleged "injury or death resulted from side effects that were *unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*" 42 U.S.C. § 300aa-22(b)(1) (emphasis added). Plaintiffs' interpretation therefore does not account for all elements of the statute. *See Gilbert v. Richardson*, 264 Ga. 744, 747-48, 452 S.E.2d 476, 479 (1994) ("It is a basic rule of construction that a statute. . . should be construed 'to make all its parts harmonize and to give a sensible and intelligent effect to each part.'" (citation omitted)). By its express terms, the statute immunizes vaccine manufacturers from liability for side effects that inevitably occur even though a vaccine is properly prepared in every respect according to its approved design specifications and is properly labeled. Thus, a manufacturer that properly prepares and labels a vaccine in accordance with the applicable federal law is immune from civil liability for side effects that nonetheless occur, even if, theoretically, an alternatively-designed vaccine might have prevented the alleged injury.

To date, two other cases have addressed the pre-emptive impact of the Vaccine Act on claims arising from vaccine-related injuries attributed to FDA-approved pediatric vaccines, *Blackmon v. American Home Products Corp.* and *Militrano v. Lederle Laboratories*. This Court's interpretation of Section 22 is in accord with the holdings of both *Blackmon* and *Militrano*. *See Blackmon v. American Home*

Prods. Corp., 328 F. Supp. 2d 659, 663-66 (S.D. Tex. 2004) (holding that Section 22(b) forecloses all design defect claims against vaccine manufacturers); *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839, 845 (Sup. Ct. Kings Co. 2003) (holding that Section 22(b) bars all design defect claims because "Congress did not intend that national vaccine policy be determined by the vagaries of a jury's determination on a case-by-case basis").

Plaintiffs contend that the Georgia Court of Appeals in *Bryant v. Hoffman-LaRoche, Inc.* has already decided that federal law does not pre-empt civil actions alleging injury caused by defectively designed prescription drugs, including vaccines. *Bryant*, however, did not mention, much less interpret, the Vaccine Act, and thus could not have decided whether the Vaccine Act bars design defect claims arising out of a *vaccine-related injury*. *See Bryant v. Hoffman-LaRoche, Inc.*, 262 Ga. App. 401, 585 S.E.2d 723 (2003). Indeed, *Bryant* involved the heart medication Posicor, not a pediatric vaccine. *See id.* at 401, 585 S.E.2d at 725. *Bryant* held that Georgia courts should determine whether a prescription drug is "unavoidably unsafe" under Comment k of Section 402A of the Restatement (Second) of Torts on a case-by-case basis. *See id.* at 406; 585 S.E.2d at 728.

While Congress clearly looked to the principles contained in Comment k of Section 402A of the Restatement (Second) of Torts when drafting Section 22(b) of the Vaccine Act, Congress did not codify the exact language of Comment k or adopt the interpretation some Georgia courts have given to

Comment k.[4] *Compare* Restatement (Second) of Torts § 402A cmt. k (2002) (stating, with respect to a vaccine, that "[s]uch a[n unavoidably unsafe] product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous") *with* 42 U.S.C. § 300aa-22(b)(1) (providing that "[n]o vaccine manufacturer shall be liable" for alleged "injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."). Nor did Congress leave vaccine design standards open to reexamination under the laws of each state, with the potential for interstate conflict: the Vaccine Act sets one rule, applicable nationwide, that pre-empts design defect claims.

Congress intended that "the principle in Comment K regarding 'unavoidably unsafe' products, *i.e.*, those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the [Act] and *that such products not be the subject of liability in the tort system*." 1986 U.S.C.C.A.N. at 6367

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[4] Comment k and Section 22(b)(1) differ in two notable aspects. First, Comment k refers to "unavoidably unsafe" products, while Section 22(b)(1) does not use that term. Second, while Comment k's language is directed to strict liability claims, Section 22(b)'s plain language is all-encompassing, including claims grounded in negligence, as well as those based on strict liability. Section 22(b)(1)'s statement that "no manufacturer shall be liable in a civil action for damages" plainly bars all claims based on the alleged design defect, whether characterized as negligence, strict liability, or by any other legal label. *See Blackmon*, 328 F. Supp. 2d at 665-66.

(emphasis added). Thus, the view of Comment k that Congress adopted when it enacted Section 22(b) immunizes manufacturers of "properly prepared" products that are "accompanied by proper directions and warnings" from all design defect claims. That statutory standard, not the common law case-by-case approach advocated by certain Georgia courts, governs the Court's analysis here. *See Militrano*, 769 N.Y.S.2d at 845 (stating that "the language in the House Committee report supports the conclusion that Congress intended to view Comment k and the [Vaccine] Act as immunizing vaccines from liability for design defects.").

The legislative history of Section 22 that is contemporaneous with that 1986 enactment confirms Congress's intention as expressed in Section 22(b):

> Given the existence of the compensation system in [the Vaccine Act], the Committee strongly believes that Comment k is appropriate and necessary as the policy for civil actions seeking damages in tort. Vaccine-injured persons will now have an appealing alternative to the tort system. *Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.*

H.R. Rep. No. 99-908, 99th Cong., 2d Sess. (1986), at 4, *reprinted in* 1986 U.S.C.C.A.N. 6344, 6367 (emphasis added); *see also Blackmon*, 328 F. Supp. 2d at 665 (finding that the relevant legislative history "rather clearly" indicates that the Act bars design defect claims).[5]

The intent to establish one national standard for vaccine design and to remove that from the purview of state tort law is further demonstrated by the Vaccine Act's specific delegation of questions of vaccine safety to the Secretary of Health and Human Services. *See* 42 U.S.C. § 300aa-27; *see also* 42 U.S.C. § 300aa-2(a)(2) (directing HHS to coordinate and direct programs to develop safe and

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[5] Plaintiffs rely on statements from a subcommittee report from 1987, the year after enactment of the Vaccine Act, as evidence of Congress's intent, in 1986, in adopting the Act. See H. R. Rep.100-391(I), at 691, reported in 1987 U.S.C.C.A.N. at 2313 365. The Court concludes that the 1987 statements are not entitled to any weight. Post-enactment statements are not reliable indicators of earlier congressional intent, particularly where, as here, they do not relate to any legislation passed at the time that the statements are made. *See, e.g., Pension Benefit Guar. v. LTV Corp.*, 596 U.S. 633, 650 (1990) ("[S]ubsequent legislative history is a 'hazardous basis for inferring the intent of an earlier' Congress"); *see also Ewing & Thomas, P.A. v. Heye*, 803 F.2d 613, 616 (11th Cir. 1986). The 1987 statements, as interpreted by Plaintiffs, directly contradict the 1986 legislative history of Section 22 cited above, which explicitly rejects Plaintiffs' argument that Section 22(b)(1) permits design defect claims. Furthermore, the statements do not assist the Court in construing Section 22(b)(1) because the statements do not track the language of Section 22(b)(1), referring instead to "unavoidably unsafe" vaccines.

effective vaccines).[6] Section 27 mandates that HHS "promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 27, 1987, and promote the refinement of such vaccines." *Id.* § 300aa-27(a)(1). It further directs the Secretary to "make or assure improvements . . .in the licensing, manufacturing, processing, testing, labeling, warning, . . . and research on vaccines, in order to reduce the risks of adverse reactions to vaccines." *Id.* § 300aa-27(a)(2). Section 27 also directs HHS to "establish a task force on safer childhood vaccines," consisting of "the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control," which is to consult with the Advisory Commission on Childhood Vaccines to make recommendations to increase vaccine safety and efficacy. *Id.* § 300aa-27(b).

The FDA's authority to determine the uniform national design for childhood vaccines would be

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[6] *See also* 42 U.S.C. § 300aa-1 ("The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines."); *Id.* § 300aa-5 (establishing the National Vaccine Advisory Committee, which, *inter alia*, studies and recommends "ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States); *Id.* § 300aa-19 (establishing the Advisory Commission on Childhood Vaccines to, *inter alia*, "advise the Secretary in implementing the Secretary's responsibilities under section 300aa-27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions.").

undermined if these Plaintiffs were allowed to challenge vaccine design under Georgia law (or under any state's law). Section 22(b) is properly read to foreclose all design defect claims against vaccine manufacturers in order to prevent plaintiffs from mounting such a collateral attack on FDA decisions through the tort system.

Accordingly, this Court enters summary judgment dismissing all of Plaintiffs' design defect claims. The dismissal of Plaintiffs' design defect claims is not limited to Plaintiffs' strict liability design defect and negligent design claims. Plaintiffs' failure to warn, fraud, gross negligence, and breach of warranty claims are also barred by Section 22(b)(1) to the extent that those claims are based solely on the inclusion of thimerosal in the design of the vaccines at issue.

D. *Plaintiffs' Failure-To-Warn Claims*

The Vaccine Defendants argue that Section 22(c) of the Vaccine Act explicitly forecloses Plaintiffs' claims based on a duty to provide direct warnings to Plaintiffs and the general public. Section 22(c) provides that:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential

> dangers resulting from the administration of the vaccine manufactured by the manufacturer.

42 U.S.C. § 300aa-22(c). To the extent that Plaintiffs' failure-to-warn claims are based on allegations that the Vaccine Defendants failed to warn Plaintiffs or the public generally, they are hereby dismissed.

The Vaccine Defendants further argue that all of Plaintiffs' failure-to-warn claims restate their design defect claims. Plaintiffs' Complaint alleges that thimerosal is a "powerful and dangerous neurotoxin poison." Compl. ¶ 9. The Vaccine Defendants contend that Plaintiffs' theory is no warning could have made safe any universally-administered childhood vaccine containing what is alleged to be a "dangerous neurotoxin poison."

In order for Plaintiffs to allege a valid failure-to-warn claim, they must assert that the vaccines at issue could have been sold safely if they contained a warning about thimerosal. *See Center Chem. Co. v. Parzini*, 234 Ga. 868, 870, 218 S.E.2d 580, 582 (1975). As currently pled, Plaintiffs' failure-to-warn claims are essentially a restatement of their design defect claims, which are barred by Section 22(b)(1) of the Vaccine Act. The Court concludes, however, that Plaintiffs should have another opportunity to plead a failure-to-warn claim that could satisfy the notice pleading standard of O.C.G.A. § 9-11-8. Therefore, the Court **GRANTS** Plaintiffs leave to replead this claim by way of an amended Complaint to be filed with the Court within fifteen (15) days of the date of

this Order. The amended Complaint should assert allegations beyond the fact that the vaccines at issue contain thimerosal and should also clarify the nature of the warnings that Plaintiffs contend the vaccines at issue required.[7] Plaintiffs should be afforded the opportunity to conduct discovery related to their amended failure-to-warn claims that is consistent with the provisions of Section 22(b)(2) of the Vaccine Act. The Vaccine Defendants, however, may present another motion for summary judgment on Plaintiffs' failure-to-warn claims after discovery pertinent to that issue has been conducted.

E. *Plaintiffs' Manufacturing Defect Claims*

The Vaccine Defendants argue that Plaintiffs have failed to allege a valid manufacturing defect claim. Plaintiffs' Complaint simply states that the vaccines were "defectively designed, manufactured, marketed and distributed." Compl. ¶ 28. Plaintiffs disagree, contending that they have adequately plead a manufacturing defect claim and that they are entitled to conduct discovery with regard to that claim.

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[7] Plaintiffs allege in their complaint that the Vaccine Defendants "impliedly and expressly warranted to the Plaintiffs that these Thimerosal-containing products . . . were safe, when in fact, the products were not safe. Each of [the Vaccine Defendants] was negligent for distributing a defective product without providing adequate warnings and without first determining that the products were safe." Compl. ¶ 53. In light of this Court's ruling that Section 22(b)(1) bars all design defect claims, Plaintiffs' breach of warranty claim would only be viable to the extent it alleges that the vaccines at issue were defective due to inadequate warnings.

"[A] manufacturing defect will always be identifiable as a deviation from some objective standard or a departure from the manufacturer's specifications established for the creation of the product." *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1236 (N.D. Ga. 2002). Because thimerosal is part of the FDA-approved formula for the vaccines at issue, Plaintiffs cannot contend that the inclusion of thimerosal was a manufacturing defect in the vaccines at issue and the cause of Plaintiffs' injuries. To the extent that Plaintiffs' manufacturing defect claims are based on the inclusion of thimerosal, they are barred by Section 22(b) as repackaged design defect claims. The Court concludes, however, that Plaintiffs' manufacturing defect allegations satisfy the notice pleading requirements set forth by O.C.G.A. § 9-11-8. Plaintiffs would need to prove a defect in manufacturing, to sustain their claim, and not just that the vaccine contained thimerosal as part of its formula. The Vaccine Defendants may present another motion for summary judgment on Plaintiffs' manufacturing defect claims after discovery pertinent to that issue has been conducted.

F. *Plaintiffs' Fraud-Based Claims, Gross Negligence Claim, And Punitive Damages Claim*

The Vaccine Defendants have moved to dismiss Plaintiffs' fraud-based claims on the ground that they contain unspecified and unattributed allegations of fraud that do not meet the standard set forth by O.C.G.A. § 9-11-9(b). *See R.W. Holdco, Inc. v. Johnson*, 267 Ga. App. 859, 866, 601 S.E.2d

177, 185 (2004). While the Complaint lacks any reference to particular false statements made or specific information concealed, and groups all defendants together into conclusory paragraphs, *See* Compl ¶¶ 46, 47, the Court will allow Plaintiffs fifteen days from the date of this Order to replead by way of an amended Complaint to be filed with the Court within fifteen (15) days of the date of this Order.[8]

For the same reasons, Plaintiffs have leave to replead their gross negligence and punitive damage claims. The Vaccine Act precludes the imposition of punitive damages on vaccine manufacturers absent a showing of "fraud or intentional and wrongful withholding of information" during the regulatory process or "other criminal or illegal activity relating to the safety and effectiveness of vaccines." 42 U.S.C. § 300aa-23(d)(2). Such claims must be pled in accordance with the particularity requirements of O.C.G.A. § 9-11-9(b). Plaintiffs shall have fifteen (15) days from the date of this Order to file an amended Complaint.

G. *The Parent Plaintiffs' Claims*

Plaintiffs argue that even if minor plaintiff's claims are barred, the parent plaintiffs' claims for

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[8] The Vaccine Defendants allege that there is an issue of whether Plaintiffs have standing to allege their fraud claims here. Pursuant to Section 22(c) of the Vaccine Act, the Vaccine Defendants argue that they have no duty to warn Plaintiffs or the general public of any potential dangers resulting from the administration of the vaccines at issue.

loss of services, infliction of emotional distress, and medical expenses incurred for minor plaintiff are not subject to the liability limitations of Section 22(b). This argument ignores the plain language of Section 22(b), which expressly extends to *any* "civil action [against a vaccine manufacturer] for damages arising from a vaccine-related injury" associated with a vaccine administered after October 1, 1988. *See* 42 U.S.C. § 300aa-22(b)(1). Because the parent plaintiffs' claims necessarily arise from minor plaintiff's alleged "vaccine-related injury," they are subject to the liability limitations of Section 22(b)(1) of the Act by its explicit terms. The case relied upon by Plaintiffs, *Moss v. Merck & Co.*, 381 F.3d 501 (5th Cir. 2004), is inapposite. That case concerned whether the pre-suit administrative exhaustion provisions imposed by Section 11 of the Vaccine Act extended to independent parental claims that could not be presented in Vaccine Court. Id. at 504-05. It does not matter, for purposes of applying Section 22, whether or not the parent plaintiffs' claims could or could not have been asserted in administrative compensation proceedings. Therefore, these claims are **DISMISSED WITH PREJUDICE**.

CONCLUSION

For the reasons stated above, Defendants Wyeth (f/k/a American Home Products Corporation), SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and GlaxoSmithKline Biologicals s.a.'s Motion for Summary Judgment, or Alternatively, Motion to Dismiss or Require Repleading of Allegations is hereby **GRANTED IN PART** and **DENIED IN PART**. Plaintiffs' design

defect claims are **DISMISSED WITH PREJUDICE** pursuant to Section 22(b)(1) of the Vaccine Act. Plaintiffs' failure-to-warn claims are hereby **DISMISSED WITH PREJUDICE** to the extent that they allege a failure to warn Plaintiffs or the general public. The remainder of Plaintiffs' failure-to-warn claims, in addition to their fraud, gross negligence, and punitive damage claims are hereby **DISMISSED WITHOUT PREJUDICE** with leave to replead. Plaintiffs' breach of warranty claims are **DISMISSED WITH PREJUDICE** to the extent that they allege that the vaccines at issue were defective solely due to their design. The claims alleged individually by the parent plaintiffs are **DISMISSED WITH PREJUDICE** pursuant to Section 22(b)(1) of the Vaccine Act. To the extent that Plaintiffs' manufacturing defect claims are based on the inclusion of thimerosal in the vaccines at issue, they are hereby **DISMISSED WITH PREJUDICE**. As there is no just reason for delay, it is directed that final judgment be immediately entered on the claims herein dismissed with prejudice. The Vaccine Defendants' motion for summary judgment on the remainder of Plaintiffs' manufacturing defect claims is **DENIED**.

SO ORDERED this 30th day of November, 2005.

/s/ Susan B. Forsling

SUSAN B. FORSLING
Judge, State Court of
Fulton County

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MAY 8 - 2009
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No. 08-1120

IN THE
Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, ET AL.,
Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI,
INDIVIDUALLY AND AS PARENTS AND NEXT FRIEND OF
STEFAN R. FERRARI,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

BRIEF IN OPPOSITION FOR RESPONDENTS

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May 8, 2009

QUESTION PRESENTED

Whether the Georgia Supreme Court correctly held that § 22 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22, does not preempt all design defect claims against vaccine manufacturers.

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INTRODUCTION

In 1986, Congress enacted the National Childhood Vaccine Injury Act ("NCVIA" or "Act") to compensate children who were the victims of tragic vaccine-related injuries through a no-fault administrative compensation system that provides expeditious recovery to injured children and their families. Congress never intended, however, for the administrative compensation scheme to be an exclusive remedy. Instead, the Act explicitly preserves victims' right to bring a civil lawsuit if they are dissatisfied with the administrative compensation route.

Rather than broadly preempt state tort remedies, Congress carved out a narrow limitation on vaccine manufacturers' civil tort liability under state law in § 22 of the Act. Specifically, § 22(b)(1) provides that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death . . . if the injury or death resulted from side effects that were *unavoidable* even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1) (emphasis added).

After a careful review of the language of § 22, as well as the legislative history, structure, and purposes of the Act, the Georgia Supreme Court correctly held that § 22 precludes state tort liability for a design defect only if the defendant shows that a particular vaccine's side effects are "not avoidable" "by a feasible design alternative" – *i.e.*, "unavoidable." Pet. App. 11. Indeed, Petitioners' contrary view – that § 22 categorically exempts vaccine manufacturers from design defect claims – not only is inconsistent with the plain language of § 22, which covers only vaccines whose side effects are "unavoidable,"

but also would create an enormous loophole by insulating vaccine manufacturers from liability even where the injurious side effects could have been avoided by better product design. The court below therefore ruled that it was premature to conclude that Respondents' design defect claim – which relates to injuries caused by vaccines containing the mercury-based preservative thimerosal – was preempted by the Act. It reversed the trial court's grant of summary judgment to Petitioners and remanded for further proceedings.

This Court should deny certiorari for four reasons. First, this Court lacks jurisdiction over the Georgia Supreme Court's interlocutory order. Despite Petitioners' contention, jurisdiction is not proper under this Court's fourth exception in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), because two of its three prongs are not met. Specifically, reversal by this Court would not necessarily preclude Respondents' design defect claim, and review by this Court at this juncture is not necessary to vindicate federal policies under the NCVIA.

Second, there is no clear split of authority on the scope of preemption under § 22 of the Act. Only one other decision by a United States court of appeals or the highest court of a state has considered the question. That decision – the Third Circuit's recent decision in *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *petition for reh'g denied*, No. 07-3794 (May 6, 2009) – disagreed with certain aspects of the analysis of the Georgia Supreme Court below and stated in *dicta* that all design defect claims, even those based on side effects that could have been avoided through feasible design alternatives, are preempted by § 22. However, the *Bruesewitz* court

acknowledged significant doubts about its own conclusion, because of ambiguities in the text and legislative history of the Act that it could not fully resolve. Ultimately, the court's holding rested on a much narrower ground — namely, that the particular vaccine at issue in that case (diphtheria-pertussis-tetanus, or DPT) had already been singled out by Congress in 1986 as falling within the class of vaccines whose side effects were "unavoidable." That narrow holding is consistent with the decision below, which held that preemption should be assessed on a product-specific rather than an industry-wide basis.

Moreover, the interlocutory posture of this case further weakens the claimed split and the need for this Court's intervention at this juncture. All the Georgia Supreme Court ruled, in reversing the trial court's grant of summary judgment, is that it is premature to find that a design defect claim is preempted by the NCVIA because there has been no showing that the vaccine is, in fact, *unavoidably* unsafe. Petitioners, on remand, will still have the right to defend the case on numerous grounds, including that the side effects of vaccines containing thimerosal were, in fact, unavoidable. Moreover, if Respondents were to prevail, and obtain a final judgment, Petitioners would have the ability to seek this Court's review of the preemption issue then. At that point, this Court would have the benefit of not only further percolation in the lower courts but also a fully developed factual record that will aid the Court's decision.

Third, given the lack of a well-developed split, and the paucity of authority on the issue, certiorari is inappropriate, and further percolation is warranted. Despite Petitioners' assertions about the supposed parade of horribles that will follow if certiorari is

denied, there is no credible evidence to suggest that the lone decision of the Georgia Supreme Court portends a public health crisis and much evidence to suggest the contrary.

Finally, certiorari is unwarranted because the Georgia Supreme Court correctly interpreted the Act. The preemption clause applies to a narrow subset of cases. Not only did the responsible Congressional committee unequivocally state that the Act does not bar *all* design defect claims, but it rejected an amendment that would have created precisely that categorical exemption. Moreover, Congress explicitly borrowed the concept of "unavoidable" side effects from comment k to § 402A of the Restatement (Second) of Torts (1965), which courts had long construed to require a product-specific analysis of whether a particular product is actually *incapable* of being any safer. The court below thus correctly held that Respondents' design defect claims were not preempted absent such a showing, which has not been made in this case.

STATEMENT OF THE CASE

The National Childhood Vaccine Injury Act

In the 1980s, Congress became concerned about the unpredictability of compensation for children who have been injured by vaccines, from the perspective of both the children as well as the vaccine manufacturers. After significant debate, Congress enacted the NCVIA, in an effort to foster a comprehensive approach to securing the vaccine supply, promoting future development, and adequately compensating innocent victims.

Among Congress's principal concerns in passing the NCVIA was the need to compensate children who had experienced debilitating vaccine-related injuries.

The Report of the House Committee on Energy and Commerce ("Energy and Commerce Committee"), which had primary responsibility for the bill, expressly noted the problem that too few injured children could receive adequate compensation under the traditional tort system.

> [T]he opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered. Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the vaccine manufacturer. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs – including attorneys' fees and court payments – are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.

H.R. Rep. No. 99-908, at 6 (1986) ("1986 Report"), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6347.

In addition to compensating victims, Congress also sought to alleviate the uncertainty that vaccine manufacturers had been experiencing in the tort system. To address these twin concerns, Congress created a new, no-fault administrative regime for addressing injuries caused by vaccines.

Under this regime, an injured child and his family must bring a claim, in the first instance, to the so-called Vaccine Court, a division of the Court of Federal Claims. *See* 42 U.S.C. § 300aa-12. The Act requires that a special master of the Court of Federal Claims (i.e., the Vaccine Court) consider the petition in an administrative (rather than an adversarial) setting, make findings of fact and conclusions of

law, and issue a decision within 240 days. *See id.* § 300aa-12(d). If the injury is included on the statute's Vaccine Injury Table, then the burden of proof shifts – the manufacturer must demonstrate, through a preponderance of evidence, that the injury is "unrelated to the administration of the vaccine." *Id.* § 300aa-13(a)(1)(B). After a decision by the special master issues, either party may seek review before the Court of Federal Claims. *See id.* § 300aa-12(e). Thereafter, either party may appeal the decision of the Court of Federal Claims to the Federal Circuit. *See id.* § 300aa-12(f).

Congress made clear its aspiration that the new system would incentivize victims to seek relief in the Vaccine Court, rather than state court, thereby promoting more expeditious compensation for victims and enhancing predictability for manufacturers.

> [T]he speed of the compensation program, the low transaction costs of the system, the no fault nature of the required findings, and the relative certainty and generosity of the system's awards will divert a significant number of potential plaintiffs from litigation.

1986 Report at 13, *reprinted in* 1986 U.S.C.C.A.N. 6354.

As Congress made clear, however, the new compensation system was conceived as a carrot rather than a stick. The new compensation scheme was not the exclusive remedy available to victims in the Act. Although claimants must *begin* with a petition to the Vaccine Court, § 21 permits victims to take advantage of traditional state tort remedies if either of two conditions is satisfied. First, if a claimant is dissatisfied with the special master's decision – because the special master awarded either no compensation or too

little compensation — he or she may elect to decline the award and file a civil action. *See* 42 U.S.C. § 300aa-21(a). Second, if the special master has failed to render a decision within 240 days, the victim may withdraw his or her petition and proceed to the civil courts. *See id.* § 300aa-21(b)(1), (c). The administrative system created by the NCVIA was designed to be an attractive alternative to, but not a substitute for, the traditional tort system. *See Schafer v. American Cyanamid Co.*, 20 F.3d 1, 3 (1st Cir. 1994) (Breyer, C.J.).

If an injured child and his family do seek resort to traditional state tort remedies, the Act provides for a very limited immunity from liability. The relevant preemption provision in § 22 concerns damages actions for injuries that were "unavoidable." That section provides:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(b)(1).

Apart from the limited immunity created by § 22, the Act makes clear that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." *Id.* § 300aa 22(a). The Act also prevents states from enacting or enforcing laws that prohibit traditional damages actions against vaccine manufacturers, except when the Act expressly preempts such causes of action. *See id.* § 300aa-22(e).

Although the NCVIA was passed in 1986, Congress understood at that time that one of the Act's core provisions – the no-fault compensation scheme for injured children – would not become effective until subsequent legislation was enacted to create a compensation fund. "The Act as passed did not include a source of payment for such compensation and made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation." H.R. Rep. No. 100-391(I), at 690 (1987) ("1987 Budget Report"), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-364. The following year, Congress enacted amendments to the NCVIA that also provided the funding necessary to make § 22 of the Act effective. *See id.* As with the 1986 bill, the House Energy and Commerce Committee had primary responsibility for the NCVIA amendments. *See id.*

Proceedings Below

In 1998, Respondents' son, Stefan Ferrari, received several vaccines, including the Hepatitis B, Hib, and DTaP vaccines, which Petitioners had designed and manufactured. Those vaccines contained the preservative thimerosal, the primary component of which is a derivative of the toxic metal, mercury. *See* Compl. ¶ 9. In June 1999, the Food and Drug Administration confirmed that "infants who receive Thimerosal-containing vaccines at several visits may be exposed to more mercury than recommended by Federal safety guidelines for total adult mercury exposure." *Id.* ¶ 11. The heart of the Ferraris' claim before the Vaccine Court and, later, in the state courts in Georgia is that the thimerosal-laden vaccines caused severe neurological injuries to Stefan.

In accordance with the Act's requirements, Respondents first submitted a petition to the Vaccine Court. Despite the Act's requirement that the special master render a decision within 240 days, *see* 42 U.S.C. § 300aa-12(d)(3)(A)(ii), the special master did not do so. Consequently, Respondents withdrew their petition pursuant to § 21 of the Act and proceeded to state court in Georgia on behalf of their minor son. They brought several claims against Petitioners, including design defect, fraud and deceit, negligent misrepresentation, and breach of warranty.

On July 5, 2005, the trial court heard oral argument and, in a memorandum dated November 30, 2005, granted Petitioners' motion for summary judgment in part, on the ground that § 22 of the Act preempted Respondents' design defect claim. *See* Pet. App. 40-49. The court also permitted Respondents to amend their complaint on certain other claims, and it allowed discovery to proceed on their manufacturing defect claim. *See id.* at 49-53.

Respondents appealed the trial court's preemption decision to the Georgia Court of Appeals, which reversed on July 5, 2007. *See id.* at 25-31. Relying primarily on the presumption against preemption, a unanimous panel of that court determined that § 22 does not preempt the state-law design defect claim.

In a unanimous decision dated October 6, 2008, the Georgia Supreme Court affirmed the court of appeals' judgment. The court conducted a careful analysis of the text, history, structure, and purposes of the Act and concluded that § 22 does not preempt the state-law design defect claim. *See id.* at 4-18.

First, the court focused on the language of § 22, which immunizes manufacturers from liability only "'if the [vaccine-related] injury or death resulted

from side effects that were unavoidable.'" *Id.* at 10 (quoting 42 U.S.C. § 300aa-22(b)(1)) (alteration in original). The court noted that the language is conditional, making clear that manufacturers are exempt only if the vaccine is "unavoidabl[y]" unsafe. *Id.* at 10-11. The court also noted that Congress explicitly borrowed the "unavoidable" formulation from comment k to § 402A of the Restatement (Second) of Torts, which applies only to "products which, in the present state of human knowledge, are quite incapable of being made safe." Restatement (Second) of Torts § 402A cmt. k. The court observed that a broad reading of the preemption clause – namely, that *all* design defect claims are preempted – would effectively read the word "unavoidable" out of the statute. Pet. App. 11. Accordingly, the court held that § 22 preempts only a narrow subset of design defect claims – i.e., claims for injuries from side effects that are unavoidable in that they could not have been eliminated through better design. *See infra* pp. 28-31.

In addition to the plain language of the statute, the Georgia Supreme Court also looked to the legislative history of the NCVIA. The court noted that in 1987, in considering the amendments that were necessary to make § 22 effective, the Energy and Commerce Committee stated that it was not prejudging whether (or which) vaccines were unavoidably unsafe in adopting the language of comment k. Specifically, the court pointed to language in the 1987 Budget Report in which the Energy and Commerce Committee "stresse[d] that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. *This question is left to the courts to determine*

in accordance with applicable law." 1987 Budget Report at 691 (emphasis added), *reprinted in* 1987 U.S.C.C.A.N. 2313-365. Moreover, the court also noted that "an amendment to the Vaccine Act which would have established 'that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.'" Pet. App. 14 (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365) (alteration in original).

Finally, the Georgia Supreme Court found that its analysis of the text and legislative history was "consistent with the structure and purpose of the Vaccine Act as a whole." *Id.* at 15. Because the Act does not make the administrative compensation system an exclusive remedy, the court found that it was important not to "'overstate the degree of uniformity'" intended by Congress. *Id.* (quoting *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 450 (2005)). The Georgia Supreme Court thus held, based on the text, history, structure, and purposes of the Act, that § 22 does not preempt the Ferraris' state-law design defect claim, absent a showing that the side effects of the vaccines at issue were, in fact, unavoidable.

REASONS FOR DENYING THE PETITION

This Court should deny certiorari for four reasons. First, this Court lacks jurisdiction to review the interlocutory order of the Georgia Supreme Court under the fourth *Cox* exception. Second, no mature split of authority exists on the question presented because the Third Circuit panel's decision in *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *petition for reh'g denied*, No. 07-3794 (May 6, 2009), is not in square conflict with the decision below. Moreover, the interlocutory posture of this case further weakens any potential split and militates against this Court's intervention at this juncture. Third, Petitioners' claims of vaccine shortages and a health-care crisis are overblown and fail to justify this Court's intervention in the absence of a mature split. Finally, certiorari is unwarranted because the Georgia Supreme Court correctly interpreted the Act.

I. THIS COURT LACKS JURISDICTION TO REVIEW THE DECISION BELOW

Congress's statutory grant of jurisdiction to review the decisions of state courts extends only to "[f]inal judgments or decrees." 28 U.S.C. § 1257(a). This Court has held that it may review a non-final judgment of a state court only in "exceptional situations." *Nike, Inc. v. Kasky*, 539 U.S. 654, 658 (2003) (Stevens, J., concurring) (internal quotation marks omitted). Petitioners claim that this Court has jurisdiction under the fourth exception under *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469 (1975), which applies where (1) "the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds," (2) "reversal of the state court on the federal issue would be preclu-

sive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come," and (3) "refusal immediately to review the state court decision might seriously erode federal policy." *Id.* at 482-83.

Here, however, neither the second nor the third prerequisite under *Cox* is met. First, reversal of the Georgia Supreme Court's decision would not necessarily preclude Respondents' design defect claims altogether. There are at least two ways in which this Court could reverse the decision below. It could decide, as Petitioners urge, that § 22 of the Act preempts *all* design defect claims, whether based on negligence or strict liability. Alternatively, however, it could decide that design defect claims are not preempted to the extent they are predicated on proof of negligence, as opposed to a theory of strict tort liability. *See Bruesewitz*, 561 F.3d at 246-47 (noting ambiguity as to "whether subsection (b) preempts all design defect claims or only strict liability design defect claims"). While a merits opinion adopting the latter approach would reverse the decision below, it would do so without "preclu[ding]" Respondents' design defect claim. *Cox*, 420 U.S. at 482-83.

This Court found that it lacked jurisdiction in an analogous situation in *Nike, Inc. v. Kasky*, *supra*. There, Nike sought review of an interlocutory order of the California Supreme Court refusing to dismiss a false-advertising claim, on the ground that the speech at issue was protected by the First Amendment. This Court dismissed the petition for certiorari as improvidently granted. As Justice Stevens explained in his concurring opinion, the Court lacked

jurisdiction over the case, because, even "if [the Court] were to reverse, [it] might hold that the speech at issue . . . [wa]s subject to suit only if made with actual malice." 539 U.S. at 660 (Stevens, J., concurring). That would not preclude the false-advertising claim altogether, but merely "control[] the nature and character of . . . the state proceedings still to come." *Cox*, 420 U.S. at 482-83. Likewise, here, this Court might hold that injuries caused by defective vaccine design are subject to suit only if the design was negligent, but not based on strict liability. That would not completely preclude Respondents' design defect claim, but merely dictate Respondents' burden of proof. As was the case in *Nike*, because "an opinion on the merits could take any one of a number of different paths," at least one of which would not preclude the underlying cause of action, this Court lacks jurisdiction under the fourth *Cox* exception. 539 U.S. at 656 (Stevens, J., concurring).

The fourth *Cox* exception also does not apply here because "refusal *immediately* to review the state court decision" will not "seriously erode federal policy." *Cox*, 420 U.S. at 483 (emphasis added). This Court created the fourth *Cox* exception to address the limited set of cases where failure to review in a particular case – despite its interlocutory posture – would frustrate this Court's review of an important federal question. *Cf. Nike*, 539 U.S. at 657 (issue was whether First Amendment precluded plaintiffs' particular false-advertising claim). As Petitioners themselves highlight, however, the issue of preemption under § 22 – while not frequently litigated – has been the subject of litigation in a variety of federal courts. *See* Pet. 26-27. This Court is thus likely in a future case to have the ability, if necessary, to review

the question of preemption under § 22 on appeal of a final judgment. Because denial of certiorari in this case will not cause the issue of preemption under § 22 to evade this Court's review, this Court lacks jurisdiction under the fourth *Cox* exception.

II. THERE IS NOT A MATURE DIVISION OF AUTHORITY ON THE QUESTION PRESENTED

A. The Third Circuit's Decision in *Bruesewitz* Does Not Create a Split on the Question Whether § 22 of the Act Preempts All Design Defect Claims Against Vaccine Manufacturers

Besides the Georgia Supreme Court, the only other highest state court or federal circuit court to have addressed the question of preemption under § 22 of the Act is the Third Circuit in *Bruesewitz*.[1] That decision, however, does not create a clear split with the decision below and thus does not warrant this Court's intervention. Although the Third Circuit made statements disagreeing with the decision below and suggesting that design defect claims against *all* vaccine manufacturers were preempted by § 22, the court expressed doubts about its own analysis in that regard. Ultimately, the court's only firm conclusion was that Congress clearly addressed and intended to preempt design defect claims related to the DPT vaccine, on the ground that that vaccine was "un-

[1] Although a handful of other courts have addressed the question whether § 22 of the Act preempts design defect claims, those courts have been federal district courts and state trial or intermediate appellate courts. As Petitioners acknowledge, a purported conflict with non-binding precedents or decisions of lower state courts is not the type of division of authority that this Court traditionally resolves.

avoidably" unsafe. That conclusion has no application to the non-pertussis vaccines involved in this case, which Congress did not specifically address.

Bruesewitz is a highly unusual opinion. The court grappled with whether § 22 preempts design defect claims as to all vaccines, as opposed to those vaccines that are determined by a state court to be unavoidably unsafe, and it stated that the evidence before it suggested that it did. But it admitted that it lacked critical information necessary for its statutory analysis and therefore expressed significant doubts about its analysis at every step.

First, the Third Circuit analyzed the text of § 22, in an effort to "'identify the domain expressly preempted'" by the NCVIA. 561 F.3d at 243 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484 (1996)). The court found that it was unable to "resolve from statutory text alone the scope of the express preemption provision" of § 22. *Id.* at 245. It concluded that neither the term "unavoidable" nor the "surrounding language" conclusively answers "whether all design defect claims are preempted or whether state courts may determine avoidability on a case-by-case basis." *Id.*

The court then turned to the "legislative history" of the NCVIA in an effort to resolve the perceived ambiguity. *Id.* Here, the court's uncertainty grew deeper. On the one hand, the court noted that the 1986 Report from the Energy and Commerce Committee contained some language that could be read to express an intent to preempt all design defect claims. *Id.* at 247-49.[2] It also acknowledged, on the

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[2] The 1986 Report states: "Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly,

other hand, that the 1987 Budget Report relied on by the Georgia Supreme Court squarely addressed the issue: "'The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with applicable law.'" *Id.* at 249 (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365). That same report also stated that "'[a]n amendment to establish as part of this compensation system that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act.'" *Id.* (quoting 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365).

The 1987 Budget Report unequivocally supports Respondents' position that Congress did not intend to preempt design defect claims as to all vaccines, even those that could have been made safer. Nonetheless, the *Bruesewitz* court declined to give credit to the clear statement in the 1987 report because it said it lacked certain information that was not provided to it in the parties' briefing.

First, the *Bruesewitz* court expressed confusion as to whether the reference to "the Committee" in the

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if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system." 1986 Report at 26, *reprinted in* 1986 U.S.C.C.A.N. 6367. That statement actually does not support Petitioners' preemption argument, but instead refers to the fact that, under state law, most litigants will often be unable to prove a design defect claim and that the federal compensation scheme is the best alternative.

quoted passages of the 1987 Budget Report referred to the Budget Committee or the Energy and Commerce Committee. *See* 561 F.3d at 250 ("it is unclear whether this refers to the Budget Committee or the Energy and Commerce Committee"). A thorough review of the 1987 report demonstrates, however, that, although the Budget Committee compiled and issued the report, the relevant language was written by the Energy and Commerce Committee, which held hearings on both the original legislation in 1986 and the funding amendments in 1987. In fact, the entirety of Title IV to the 1987 Budget Committee Report (pages 377 to 715) is entitled "Committee on Energy and Commerce." A letter from Rep. John Dingell, the Chairman of the Energy and Commerce Committee, to Rep. William Gray III, the Chairman of the Budget Committee, makes clear that the materials included in that section are "two Committee Prints approved by the Committee on Energy and Commerce for inclusion in the forthcoming reconciliation bill." *See* 1987 Budget Report at 380, *reprinted in* 1987 U.S.C.C.A.N. 2313-200. Had this additional information been brought to the attention of the *Bruesewitz* court, it likely would have materially altered the court's analysis.

Second, the Third Circuit appeared to doubt whether the Energy and Commerce Committee had, in fact, considered and rejected an amendment that would have eliminated liability on the grounds of "a manufacturer's failure to develop [a] safer vaccine." 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365; *see Bruesewitz*, 561 F.3d at 250 (stating that "no record is available to confirm" that this amendment was in fact rejected). Again, these doubts appear to be based on the court's un-

certainty as to whether the statements in the 1987 Budget Report – which unequivocally state that such an amendment was rejected – were properly attributable to the Energy and Commerce Committee. Had the 1987 report reflected the Budget Committee's description of an Energy and Commerce Committee markup, the Third Circuit's desire for independent confirmation might have been understandable. As described above, however, the description of the committee's rejection of the amendment is clearly attributable to the Energy and Commerce Committee itself, leaving little room for doubt that the amendment had, in fact, been considered and rejected by that committee just a year earlier.

Finally, the Third Circuit expressed skepticism about the reliability of "subsequent" legislative history. 561 F.3d at 250. Based on the same lack of understanding of the references to "the Committee" in the 1987 Budget Report, the Third Circuit failed to appreciate that the 1987 report did not constitute "subsequent" legislative history at all. Rather, as the 1987 report explains, the enactment of the NCVIA was a multi-year process. Although the Act, including the compensation system and § 22, was originally passed in 1986, those provisions did not become effective until 1987, when Congress passed the amendments to the bill and provided for its funding. *See* 1987 Budget Report at 690 (stating that "[t]he Act . . . made the compensation program and accompanying tort reforms contingent on the enactment of a tax to provide funding for the compensation" and explaining that the 1987 amendments provide that funding), *reprinted in* 1987 U.S.C.C.A.N. 2313-364. The Energy and Commerce Committee considered and oversaw both aspects of the legislation. *See id.*

at 690-91, *reprinted in* 1987 U.S.C.C.A.N. 2313-364 to -365. Given that § 22 did not become effective until the 1987 amendments were passed, and the Energy and Commerce Committee oversaw both bills, the views of that committee expressed in the 1987 Budget Report represent the views of the framers of the Act.

Despite the clear language in the 1987 Budget Report supporting Respondents' position, the Third Circuit "refuse[d] to view the relevant legislative history as containing 'dueling' committee reports." 561 F.3d at 250. That refusal did not reflect a firm conclusion but, rather, reflected the fact that the court did not have a complete understanding of the 1987 report and, in particular, lacked information as to which committee was being described in that report. *See id.* ("*[w]ithout more*, we have no basis to conclude that the [1987] Budget Report is an accurate reflection of what transpired before the Energy and Commerce Committee") (emphasis added).

Given its own professed uncertainty, the *Bruesewitz* court articulated a narrow holding. Specifically, the court held that, "*[e]ven if Congress did not intend to prohibit all design defect claims against vaccine manufacturers*, the legislative history indicates that it intended to preempt the specific claim at issue here" – namely, design defect claims against the manufacturers of DPT vaccines in particular. *See id.* (emphasis added). The court grounded that conclusion in legislative history that the Energy and Commerce Committee had specifically addressed the whole-cell pertussis vaccine as an example of a vaccine whose side effects were unavoidable. *See id.* at 250-51. The committee had noted that, although some efforts to create an acellular pertussis vaccine

were in progress, clinical trials to test such a vaccine would pose significant hurdles. *See id.* at 251.[3] Given that legislative history, the Third Circuit concluded that "Congress weighed the various concerns related to the pertussis vaccine and concluded that DPT manufacturers should be shielded from liability for injuries arising from the whole-cell pertussis vaccine." *Id.*

The *Bruesewitz* court's narrow holding is not in conflict with the decision below. In fact, that holding effectively adopts the product-specific analysis that the Georgia Supreme Court interpreted § 22 to require. Whatever Congress's intent was with respect to the whole-cell pertussis component of the DPT vaccine, Congress did not specifically address vaccines containing thimerosal when it passed the Act, and there is thus no basis to conclude that Congress expressly preempted design defect claims against the manufacturers of thimerosal-containing vaccines.

In sum, the Third Circuit's admitted ambivalence about the statutory text and the import of the legislative history suggests that its more sweeping statements about the scope of § 22 are *dicta* and do not create an actual conflict with the decision below. Further percolation is warranted because there is good reason to believe that future courts – including the Third Circuit itself – will rely on the full legislative history that was not before the *Bruesewitz* court and ultimately limit *Bruesewitz* to its narrow DPT-specific holding. At the very least, further percolation will sharpen the arguments for this Court's con-

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[3] Since 1986, vaccine manufacturers, including Petitioners, have successfully developed a safer acellular pertussis vaccine, which is now administered as part of the DTaP vaccine. The DPT vaccine is no longer used in the United States.

sideration by casting additional light on the meaning of § 22.

B. The Interlocutory Posture of This Case Further Weakens Any Conflict

The interlocutory ruling at issue further weakens any conflict. Not only does this Court lack jurisdiction because of the interlocutory posture of this case, *see supra* Part I, but the interlocutory posture also counsels against this Court's intervention at this early juncture.

In reversing the grant of summary judgment to Petitioners, the Georgia Supreme Court merely held that it was premature, in the absence of a showing that the vaccines' side effects are "unavoidable," to hold that § 22 preempts all liability for design defects. The impact of that decision will depend very heavily on what occurs on remand. There, Petitioners will be able to defend the case on numerous grounds that may result in a final judgment in their favor. For example, Petitioners may demonstrate that the side effects of thimerosal-laden vaccines are, in fact, unavoidable or that there is no causal link between thimerosal and neurological damage, either generally or in the Ferraris' specific case. If so, the import of the Georgia Supreme Court's preemption holding will be severely diminished.

If, alternatively, after further proceedings below, Respondents were to prevail, Petitioners would still have an opportunity to seek this Court's review on the preemption question. At that juncture, it is likely that further percolation will have either eliminated any conflict among the lower courts or further developed that conflict. Moreover, if the Court were to grant certiorari at that stage, the Court would have the benefit of a full evidentiary record and

further legal decisions by the courts below on which to base its decision. Finally, if the Court were to grant certiorari on the issue in an intervening case, Petitioners would not be prejudiced because the Court's holding in that case would be fully applicable to these proceedings.

Even when it has jurisdiction, this Court rarely grants certiorari in an interlocutory posture, and it does so only to resolve an important federal question deserving of urgent review. Here, there is no reason to believe that the Georgia Supreme Court's decision in this case represents the final word on the scope of § 22. Not only will the issue likely remain alive during future stages of litigation in this case, but other cases are likely to present the same legal questions. Consequently, prudential considerations militate strongly in favor of allowing further percolation, especially given the absence of a developed split of authority on the issue presented.

III. THERE IS NO PLAUSIBLE NATIONAL VACCINE CRISIS WARRANTING THIS COURT'S PREMATURE INTERVENTION

Despite a great deal of high-pitched rhetoric, Petitioners have not marshaled any credible evidence to suggest either that there has been a rush to the courthouse by vaccine litigants or that the specter of such a rush will cause a national crisis. Petitioners' suggestion that failure to grant certiorari in this case will jeopardize the availability of essential vaccines in the United States is, to say the least, a vast overstatement.

A. Petitioners Exaggerate the Increase in Vaccine-Related Court Cases

Because of the success of the Act in establishing an attractive administrative mechanism for compensa-

tion of vaccine-related injuries, as Petitioners themselves concede, "[n]o case governed by the Vaccine Act against a vaccine manufacturer has proceeded to trial – much less to verdict – in the two decades since the Vaccine Act became effective." Pet. 20-22. Petitioners nonetheless assert that a single decision in Georgia will create "devastating vaccine shortages," Pet. 19, and assert that "[n]ationwide filings are also bound to spike," Pet. 22. None of the evidence cited by Petitioners actually supports the conclusion that there is an impending crisis.

Petitioners rely in large part on a graph from an article by Geoffrey Evans, which purports to demonstrate a more severe spike in lawsuits than the surge that led to the vaccine crisis in the mid-1980s and ultimately Congressional intervention. *See* Geoffrey Evans, *Update on Vaccine Liability in the United States: Presentation at the National Vaccine Program Office Workshop on Strengthening the Supply of Routinely Recommended Vaccines in the United States, 12 February 2002*, 42 Clinical Infectious Diseases S130, S134 (2006). The recent "spike," however, is nothing more than an illusion created by aggregating data from *four* years into a single bar on the graph. On average, then, the years 2001-04 have seen the filing of fewer than 90 lawsuits per year, far below the levels that Congress faced in the mid-1980s.[4]

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[4] Furthermore, the Evans article appears to be comparing apples and oranges. Although the data for 1979 until 2000 measure the number of lawsuits filed against U.S. manufacturers of two different kinds of DPT vaccines (again, not the vaccine at issue here), the data for 2001-04 measure the filing of "lawsuits alleging the development of autism (or other neurodevelopmental disorders) as a result of vaccines." 42 Clinical Infectious Diseases at S134.

Moreover, the fact that there are some civil suits being brought against vaccine manufacturers does not represent a "crisis" from the standpoint of congressional policy. Indeed, Congress expressly *preserved* the ability of injured children to seek relief in state court. Although vaccine manufacturers, such as Petitioners, lobbied Congress to make the Vaccine Court the *exclusive* remedy for injured children and their families, Congress rejected that approach. The ebb and flow of state-court filings cited by Petitioners thus does not represent a "crisis," but rather the natural workings of the regime that Congress created when it enacted the NCVIA.

B. There Is No Evidence of an Imminent Flood of State-Court Lawsuits by Injured Children

At any rate, beyond the supposed uptick in civil filings cited by the Evans article, there is no reason to believe that there will be an unmanageable flood of new vaccine-related litigation in state courts. First, as demonstrated by the statistics published by the National Vaccine Injury Compensation Program, the number of filings in the Vaccine Court in recent years is well within normal parameters:

National Vaccine Injury Compensation Program
Post-1988 Statistics Report
As of May 1, 2009

Fiscal Year	Non-Autism	Autism	Total
FY 1988	24	0	24
FY 1989	148	0	148
FY 1990	1,492	0	1,492
FY 1991	2,718	0	2,718
FY 1992	189	0	189
FY 1993	140	0	140
FY 1994	107	0	107
FY 1995	180	0	180
FY 1996	84	0	84
FY 1997	104	0	104
FY 1998	120	0	120
FY 1999	410	1	411
FY 2000	162	1	163
FY 2001	194	22	216
FY 2002	187	770	957
FY 2003	155	2,437	2,592
FY 2004	127	1,087	1,214
FY 2005	147	588	735
FY 2006	155	170	325
FY 2007	242	168	410
FY 2008	163	253	416
FY 2009	143	88	231
Total	**7,391**	5,585	**12,976**

U.S. Dep't of Health & Human Services, Health Resources & Services Admin., *Statistics Report* (May 1, 2009), *available at* ftp://ftp.hrsa.gov/vaccinecompensation/StatisticsReport.pdf. Those data dem-

onstrate that, while there was an increase in filings in the Vaccine Court, primarily in 2003 and 2004, there have been similar periods of increased filings over the 20-year history of the Vaccine Court (1990-1991). But, notably, the number of new autism-related claims has plummeted since 2003. Moreover, the decisions by the Georgia courts do not appear to have influenced the number of filings in either the Vaccine Court or the civil courts.

The fact that there are now 4,900 vaccine-autism claimants presently in Vaccine Court does not, contrary to Petitioners' contentions (at 22), presage an impending rush to state courts. The Vaccine Court has successfully achieved Congress's goal of streamlining cases and promoting expeditious settlement of claims. Within just a few years of the Vaccine Court's inception, it had largely succeeded in providing quick remedies and sufficient compensation while drastically reducing attorneys' fees and administrative expenses, all without abrogating the traditional tort system. *See* Denis J. Hauptly & Mary Mason, *The National Childhood Vaccine Injury Act*, 37 Fed. B. News & J. 452 (1990). Indeed, the increase in Vaccine Court filings in 1990-1991, *see supra* p. 26, did not lead to a commensurate increase in civil suits in state court, *see* Pet. 21 (showing an average of 15 cases from 1990-1993).

Despite the success of the Act in avoiding the need for state tort suits, Petitioners hypothesize that the Vaccine Court will reject most of the autism-related claims and that there will be a deluge of new lawsuits in the state courts. But this is sheer speculation. There is no basis to prejudge whether the Vaccine Court will find, in test cases that are currently pending before it, that thimerosal-containing vaccines

cause certain neurological disorders, such as autism. If the Vaccine Court finds causation, the odds of a flood of state-court litigation are extremely low. Even if the Vaccine Court finds no causation, it is highly speculative whether parties will then seek to relitigate that issue in state court or, alternatively, conclude that they have had their "day in court." Ultimately, Petitioners offer no concrete evidence for their alarmist claims that a new rash of vaccine-injury claims is bound to inundate the state courts and threaten the vaccine supply of the United States. It is just as likely that the vaccine-autism cases will successfully be handled by the Vaccine Court, consistent with the success of that court over its 20-year history.

Given the absence of any evidence to support their doomsday predictions, Petitioners, in short, have failed to show that this case presents an issue of such extraordinary importance that it should be decided by this Court in an interlocutory posture and in the absence of a mature and well-developed split of authority.

IV. THE GEORGIA SUPREME COURT CORRECTLY INTERPRETED THE PREEMPTION PROVISION OF THE ACT

Contrary to Petitioners' contentions, certiorari is unwarranted because the Supreme Court of Georgia correctly interpreted § 22 of the Act based on a careful analysis of its text, history, structure, and purposes.

As the Georgia Supreme Court recognized, the language of the Act – which precludes liability only "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings," 42 U.S.C. § 300aa-22(b)(1)

– clearly requires a predicate determination that a particular vaccine's side effects are, in fact, "unavoidable." Were there any doubt left by the language of § 22, the legislative history eliminates it. As discussed above, *see supra* pp. 16-17, the committee overseeing the legislation clearly stated that the question whether a particular vaccine's side effects are unavoidable "is left to the courts to determine in accordance with applicable law." 1987 Budget Report at 691, *reprinted in* 1987 U.S.C.C.A.N. 2313-365. Indeed, the committee rejected "[a]n amendment to establish as part of this compensation system that a manufacturer's failure to develop [a] safer vaccine was not grounds for liability." *Id.* Petitioners are simply wrong that Congress "made the blanket determination that childhood vaccines are 'unavoidably unsafe' and should be categorically exempt from liability." Pet. 30.

This conclusion is further bolstered by the provenance of the language of § 22, which is based on comment k to § 402A of the Restatement (Second) of Torts, which sets forth an exception to strict liability. Both comment k itself and cases interpreting it, make clear that whether a vaccine is "unavoidably" unsafe is a determination that must be made on a product-specific basis. Comment k, by its own terms, covers only those rare products "which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) Torts § 402A cmt. k. Such products – the Pasteur rabies vaccine is cited as an example – are not subject to the strict liability standard otherwise provided for by § 402A. Instead, "[s]uch a product, properly prepared, and accompanied by proper directions and warning, is not defec-

tive, nor is it *unreasonably* dangerous." *Id.* To fall within the scope of comment k, however, a defendant must make a predicate showing that the product is, in fact, "incapable of being made safe."[5]

Congress made clear that, in codifying the principle of comment k in the Act, it understood that immunity from liability would apply only *if* the product was "unavoidabl[y]" unsafe:

> [Section 22(b)] sets forth the principle contained in Comment k of Section 402A of the Restatement of Torts (Second) that a vaccine manufacturer should not be liable for injuries or deaths resulting from unavoidable side effects even

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[5] Judicial interpretations of comment k, both before and after the Act was passed in 1986, make clear that determining whether a product is unavoidably unsafe requires an intensely factual, product-specific determination. *See, e.g., Belle Bonfils Mem'l Blood Bank v. Hansen*, 665 P.2d 118, 123 (Colo. 1983) ("[T]he manufacturer must demonstrate that at the time of the preparation or marketing of the product, the state of the art had not progressed to where the risk was no longer unavoidable, and that the product's benefits could not be achieved by a substitute product or in another manner."); *Feldman v. Lederle Labs.*, 479 A.2d 374, 382-83 (N.J. 1984) ("[W]e see no reason to hold as a matter of law and policy that all prescription drugs that are unsafe are unavoidably so. Drugs, like any other products, may contain defects that could have been avoided by better . . . design."); *Kearl v. Lederle Labs.*, 218 Cal. Rptr. 453, 463-64 (Cal. Ct. App. 1985) (requiring a product-specific showing); *Toner v. Lederle Labs.*, 732 P.2d 297, 306 (Idaho 1987) (same); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 840 (Neb. 2000) (same); *Bryant v. Hoffmann La Roche, Inc.*, 585 S.E.2d 723, 726 (Ga. Ct. App. 2003) (acknowledging and embracing majority view that comment k requires product-specific analysis); *see also Weiss v. Fujisawa Pharm. Co.*, Civil Action No. 5:05-527-JMH, 2006 WL 3533072, at *2 (E.D. Ky. Dec. 7, 2006) (collecting cases and indicating overwhelming support for a narrow, product-specific approach).

> [though] the vaccine was properly prepared and accompanied by proper directions and warnings.
>
> The Committee has set forth Comment K in this bill because it intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present state of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system. . . . [E]ven *if* the defendant manufacturer *may have* made as safe a vaccine as anyone reasonably could expect, a court or jury undoubtedly will find it difficult to rule in favor of the "innocent" manufacturer if the equally "innocent" child has to bear the risk of loss with no other possibility of recompense.

1986 Report at 25-26 (emphases added), *reprinted in* 1986 U.S.C.C.A.N. 6366-67.

Congress's clear intent was to exempt manufacturers from liability only upon a predicate showing that, in fact, they had "made as safe a vaccine as anyone reasonably could expect." *Id.* at 26, *reprinted in* 1986 U.S.C.C.A.N. 6367. It did not categorically exempt liability for all vaccine manufacturers, no matter how poorly the vaccine had been designed. Indeed, such a broad exemption is wholly inconsistent with the structure and purposes of the Act to create an attractive alternative to the traditional tort system, while preserving the right of injured children and their families to seek relief, if they choose, through the traditional tort system.

In sum, this Court lacks jurisdiction to review the decision below. Even if it had jurisdiction, certiorari would be unwarranted because there is no clear split between the decision below and the Third Circuit's

decision in *Brueseuitz*, nor any urgent reason for this Court's review in the absence of such a split. Especially given that the Georgia Supreme Court correctly interpreted § 22 of the Act, this Court's review is not warranted.

CONCLUSION

The petition for a writ of certiorari should be denied.

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IN THE
Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, ET AL.,
Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI,
INDIVIDUALLY AND AS PARENTS AND NEXT FRIEND OF
STEFAN R. FERRARI,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

SUPPLEMENTAL BRIEF FOR RESPONDENTS

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October 7, 2009

Respondents respectfully submit this supplemental brief pursuant to this Court's Rule 15.8 to advise the Court that Respondents have voluntarily dismissed their claims in the present case without prejudice and that the case is therefore moot. *See Board of License Comm'rs v. Pastore*, 469 U.S. 238, 239-40 (1985) (per curiam).

On September 21, 2009, Respondents filed a "Voluntary Notice of Dismissal Without Prejudice" in the State Court of Fulton County pursuant to Georgia Code § 9-11-41(a) and gave notice of such voluntary dismissal pursuant to § 41(a)(1)(A) of the Georgia Civil Practice Act. *See* App., *infra*, 1a-2a. Georgia courts have liberally construed plaintiffs' right to dismiss a case voluntarily and without prejudice. *See, e.g., McKesson Corp. v. Green*, 648 S.E.2d 457, 461-62 (Ga. Ct. App. 2007). Under Georgia law, the voluntary dismissal was proper and thereby terminated the present litigation.

In light of the voluntary dismissal, there is no longer a live case or controversy, such that the case is moot. Because this Court no longer has Article III jurisdiction over the case, the Court should dismiss the petition. *See DeFunis v. Odegaard*, 416 U.S. 312, 319-20 (1974) (per curiam).

This case does not fall into any of the narrowly circumscribed exceptions to the mootness doctrine. It is not "capable of repetition, yet evading review." *Southern Pac. Terminal Co. v. ICC*, 219 U.S. 498, 515 (1911). As in *DeFunis*, there is no reason that future litigation raising the same questions at issue here will evade review, unlike cases dealing with pregnancy or elections. *See DeFunis*, 416 U.S. at 318-19; *see also Roe v. Wade*, 410 U.S. 113, 125 (1973). Neither does this case involve the cessation of illegal

conduct, which a party might easily resume. *See, e.g., City of Erie v. Pap's A.M.*, 529 U.S. 277, 287-89 (2000). Finally, it does not implicate a situation in which the Court has devoted extensive resources to a case after having granted certiorari. *See Honig v. Doe*, 484 U.S. 305, 331-32 (1988) (Rehnquist, C.J., concurring).

In short, although the present case is moot, the Court will likely have ample opportunity to review the federal questions presented in the context of an actual case or controversy.

* * *

For the foregoing reasons, this Court should dismiss the petition in the present case as moot.

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October 7, 2009

APPENDIX

IN THE STATE COURT OF FULTON COUNTY
STATE OF GEORGIA

Civil Action File No. 02VS031404F

MARCELO A. FERRARI AND CAROLYN H. FERRARI, INDIVIDUALLY AND AS PARENTS AND NEXT FRIEND OF STEFAN R. FERRARI,
PLAINTIFFS

V.

AMERICAN HOME PRODUCTS CORP. ET AL.,
DEFENDANTS

[filed Sept. 21, 2009]

VOLUNTARY NOTICE OF DISMISSAL WITHOUT PREJUDICE

NOW COME PLAINTIFFS MARCELO AND CAROLYN FERRARI and give notice, pursuant to Section 41(a)(1)(A) of the Georgia Civil Practice Act, of their dismissal of the above-styled action without prejudice.

This 21st day of September, 2009.

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No. 08-1120

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

SUPPLEMENTAL BRIEF IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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RULE 29.6 STATEMENT

Petitioners SmithKline Beecham Corporation's and GlaxoSmithKline Biologicals, S.A.'s Rule 29.6 statements were set forth at page ii of the Petition for a Writ of Certiorari, and there are no amendments to those statements.

Petitioner Wyeth hereby amends its Rule 29.6 statement to state that Pfizer Inc. is the parent corporation of Wyeth and Pfizer Inc. owns 10% or more of Wyeth's stock.

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INTRODUCTION

Pursuant to Supreme Court Rule 15.8, Petitioners submit this Supplemental Brief in response to the supplemental brief recently filed by Respondents (the plaintiffs below). Respondents' trial court filing of a voluntary discontinuance *without prejudice* does not render this case moot. Notwithstanding this without-prejudice dismissal, the judgment of the Georgia Supreme Court has not been vacated and stands as a binding precedent in that state. Thus, an erroneous interpretation of the Vaccine Act continues to control post-Vaccine Court litigation in Georgia, and Respondents—whose claims derive from alleged injuries to a minor child—remain free to revive their case at any time. No precedent from this Court permits a party to both preserve the benefits of a state court ruling and shield it from review. Moreover, Respondents' procedural tactic does nothing to heal the split in the lower courts on the issue, or prevent the harm that can be expected to result from the Georgia Supreme Court's judgment. Thus, there remains an undiminished need for this Court to review the preemption question presented in the Petition.

The Court should grant certiorari in both this case and in the other pending petition that presents the same Vaccine Act preemption issue, *Bruesewitz v. Wyeth, Inc.*, No. 09-152. Alternatively, if the Court grants the writ in *Bruesewitz* only, Petitioners request that it hold this Petition pending the disposition of *Bruesewitz*.

SUPPLEMENTAL STATEMENT OF THE CASE

On June 8, 2009, the Court called for the views of the United States on the Petition in this case. 129 S. Ct. 2786 (2009). The United States has not yet filed its brief in response to the invitation.

On September 21, 2009, without any explanation, Respondents filed a voluntary notice of dismissal without prejudice in the trial court. The notice simply reads that Respondents "give notice, pursuant to Section 41(a)(1)(A) of the Georgia Civil Practice Act, of their dismissal of the . . . action without prejudice." Supp. Br. at 1a. The referenced section of the Georgia Civil Practice Act permits the filing of a voluntary dismissal "at any time before the first witness is sworn" at trial. Ga. Code Ann. § 9-11-41(a)(1)(A). Neither an order of the court nor consent of the other parties is required after issue has been joined, as would be the case under Rule 41 of the Federal Rules of Civil Procedure.

Under Georgia law, Respondents have at least nine years in which to reinstate their dismissed claims. Georgia law provides for the refiling of voluntarily dismissed claims at any time within the original applicable period of limitations or within six months of the dismissal, whichever is later. Ga. Code Ann. § 9-2-61(a). In Georgia, the statute of limitations—which is two years for personal injury actions—tolls for minors up to their 18th birthday. Ga. Code Ann. §§ 9-3-90(a); 9-3-33. The minor Stefan Ferrari was born in 1998. He may refile the case immediately, or at any time before his 20th

birthday (the age of majority plus the two year period of limitations), i.e., 2018.[1]

Respondents did not move to vacate the Georgia Supreme Court's preemption decision. For its part, the Georgia Supreme Court made clear in the opinion under review that its decision will govern post-Vaccine Court cases in Georgia unless and until this Court intervenes. *See* App. 18 (stating that the decision will remain the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue").

ARGUMENT

I. RESPONDENTS' NONPREJUDICIAL DISMISSAL DOES NOT RENDER THIS CASE MOOT.

This case is not moot because: (1) Respondents, the party seeking to render this case moot, prevailed below; (2) the voluntary nonprejudicial dismissal allows Respondents to refile the lawsuit at a time of their choosing; and (3) notwithstanding the dismissal, the Georgia Supreme Court's decision remains in effect and will continue to govern the rights of litigants, including Petitioners, in ongoing actions in the state.

When, as here, it is the prevailing party that seeks to render a case moot, there is "the potential

---

[1] The possibility exists that the statute of limitations could be tolled for an even longer period of time. If Stefan Ferrari were declared incompetent because of his autism, the accrual date of the limitations period would toll indefinitely. *See* Ga. Code Ann. § 9-3-90(a).

for gamesmanship," *Bunting v. Mellen*, 541 U.S. 1019, 1021 (2004) (opinion of Stevens, J., respecting the denial of certiorari), and the Court has recognized the possibility that the maneuvering is an attempt "to manipulate the Court's jurisdiction to insulate a favorable decision from review." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 288 (2000).

A prevailing party's withdrawal of a claim can result in a moot case only if the Court has the power to prevent gamesmanship, i.e., if the Court can order *both* a prejudicial dismissal of the claims and vacatur of the judgment below. *See Deakins v. Monaghan*, 484 U.S. 193, 201 (1988). In *Deakins*, an action filed in federal court, the equitable relief sought by the respondents (plaintiffs below) formed the basis of one of the questions upon which the Court granted certiorari. *Id.* at 201. At oral argument, however, the respondents stated that they wished to withdraw their claims for equitable relief. *Id.* at 198-99. The Court agreed with respondents that the withdrawn claims were moot because the Court had the ability "to prevent respondents from renewing their claims after they are dismissed as moot." *Id.* at 201 n.4. Specifically, the Court protected the petitioner from the risk of a renewed claim by vacating the Court of Appeals' judgment and directing the dismissal of the claims for equitable relief *with prejudice*. *Id.* at 200-01.

Here, the Court cannot ensure such protections for Petitioners. Respondents' dismissal is without prejudice, and Georgia law allows them to refile their lawsuit at any time. If the Court were to dismiss the Petition as moot, Respondents could refile the lawsuit the very next day. Respondents

bear the "'heavy burden of persuad[ing]'" the Court that they "cannot reasonably be expected" to refile their lawsuit again. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC)*, 528 U.S. 167, 189 (2000) (quoting *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203 (1968)). Respondents have not and cannot meet that heavy burden here. The only way Respondents could have shown this Court that they have decided to end this litigation conclusively would have been to file a voluntary dismissal *with* prejudice. Respondents elected not to do so.

The second *Deakins* requirement—that the judgment below be vacated is also missing here. Respondents' mootness argument, if accepted by the Court, would leave the judgment below intact because the Court has decided it can only dismiss petitions of moot cases on review from state court and cannot vacate them. *ASARCO Inc. v. Kadish*, 490 U.S. 605, 621 n.1 (1989) (stating that if a case becomes moot on review from a state court, the Court "lack[s] jurisdiction and thus also the power to disturb the state court's judgment."). As long as the judgment here remains intact, Petitioners will be saddled with an "ongoing injury"—the judgment preventing them from asserting their preemption defense in ongoing and future cases in Georgia's state courts. *See Erie*, 529 U.S. at 288. The Court has refused to consider a case moot in such a situation. *See id.* Petitioners are unaware of any case in which this Court has found the controversy moot under the circumstances present here.

The Court should not permit Respondents to avoid review of the state court decision in their favor

while maintaining the precedential authority of the decision in Georgia, particularly where it involves a question of such national importance.

II. THE COURT SHOULD GRANT CERTIORARI IN BOTH THIS CASE AND *BRUESEWITZ*, OR ALTERNATIVELY, HOLD THIS CASE PENDING THE OUTCOME OF *BRUESEWITZ*.

The Court currently has before it two petitions that present the same issue—whether the Vaccine Act's express preemption provision encompasses, and thus preempts, all design defect claims in post-Vaccine Court cases. *See Bruesewitz v. Wyeth, Inc.*, No. 09-152. In *Bruesewitz*, both petitioners and respondent Wyeth (who is also a Petitioner here) requested that the Court grant certiorari based on the split in authority on a legal issue of crucial significance to national health policy.

Petitioners here agree with the *Bruesewitz* respondents that the Court should resolve the question presented now because of the danger that the Georgia Supreme Court's decision poses to the stability of the nation's vaccine supply. The urgency of resolving the question presented is addressed in depth in the Petition, the Reply, and in the amicus briefs submitted in support of the Petition, including the amicus brief from the American Academy of Pediatrics and 10 other physician and public health organizations. If, as a result of Respondents' strategic maneuvering, the Petition is dismissed as moot, the decision below will be left in place and govern other litigation against Petitioners. The Georgia Supreme Court made clear that its decision

is—and will remain—the law of Georgia "at least until the Supreme Court of the United States has spoken on the issue." App. 18.

Petitioners respectfully request that the Court grant certiorari in both this case and *Bruesewitz*. In the event the Court were to grant review in *Bruesewitz* only, Petitioners request that the Court hold this Petition pending the outcome of *Bruesewitz*.

CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Petition and Reply, this Court should grant a writ of certiorari, or, in the alternative, hold this case pending resolution of *Bruesewitz*.

Respectfully submitted,

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IN THE

Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE AND GLAXOSMITHKLINE BIOLOGICALS, S.A.,

Petitioners,

v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,

Respondents

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RULE 29.6 STATEMENT

Petitioners' Rule 29.6 statements were set forth at page ii of their Petition for a Writ of Certiorari, and there are no amendments to those statements.

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INTRODUCTION

Since the filing of the Petition, the United States Court of Appeals for the Third Circuit has supplied an extra ingredient that makes this case even more cert-worthy: It issued a decision that presents a clear and intractable conflict between a state's highest court and a federal court of appeals on the question presented by the Petition. In *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 251 (3d Cir. 2009), the Third Circuit held that the Vaccine Act categorically preempts all design defect claims. That is the opposite of what the Georgia Supreme Court held in this case. The Third Circuit explicitly considered and rejected the Georgia Supreme Court's analysis of Section 22 of the Vaccine Act. The Third Circuit further explained that the Georgia Supreme Court's construction of Section 22 threatened to destabilize the vaccine market, just as the Petition and the supporting *amicus* briefs argue.

This clear split between a state supreme court and a circuit court—on a question of law that is of critical importance to national public health policy—warrants this Court's review. The issue must be resolved now to prevent the very litigation crisis Congress averted by passing the Vaccine Act.

I. THE THIRD CIRCUIT'S RECENT DECISION CONFLICTS DIRECTLY WITH THE GEORGIA SUPREME COURT'S DECISION BELOW.

The Third Circuit in *Bruesewitz* and the Georgia Supreme Court in this case each confronted the same pure legal question—whether the Vaccine Act

categorically preempts all design defect claims—and came to diametrically opposite conclusions. As in this case, the plaintiffs in *Bruesewitz* argued that the vaccine-related injury could have been avoided by a vaccine design that they contend would have been safer than the one approved by the FDA. *Bruesewitz*, 561 F.3d at 237. The Third Circuit (joining every court outside Georgia) held that the Vaccine Act expressly preempts "all design defect claims." *Id.* at 248; Pet. at 26-27.

The Third Circuit concluded that the statutory text, structure, and legislative history of Section 22 showed "a 'clear and manifest' expression of congressional intent" to preempt design defect claims. *Bruesewitz*, 561 F.3d at 246, 251. The Third Circuit further found that the 1986 House Committee on Energy and Commerce Report supported this conclusion. The Committee Report "repeatedly stressed the importance of vaccine development and availability"; "emphasized that the new system would reduce and stabilize litigation costs"; and "explicitly stated that injured individuals could only seek redress in the state tort system for certain manufacturing defect and warning claims." *Id.* at 248-49.

In so ruling, the Third Circuit rejected the Georgia Supreme Court's analysis, politely noting that it did "not consider the *Ferrari* Court's reading [of Section 22] to be compelling." *Id.* at 246. Contrary to plaintiffs' contention, the unanimous Third Circuit panel did not "express[] doubts about its own analysis" (Opp. at 15) and it certainly did not "effectively adopt[] the product-specific analysis that the Georgia Supreme Court interpreted § 22 to

require." Opp. at 21. The Third Circuit stated that the Georgia Supreme Court's "construction [of Section 22] is contrary to the structure of the Act because it does not bar any design defect claims. If we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Bruesewitz*, 561 F.3d at 246. The court further found that "[e]ach of the objectives [of the Vaccine Act] extolled by the Commerce Report would be undermined if design defect claims were permitted under the statute," leading to the "very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act." *Id.* at 249. Specifically, such a construction "would undoubtedly increase the costs and risks associated with litigation and would undermine a manufacturer's efforts to estimate and control costs." *Id.*

Contrary to plaintiffs' assertion, this was not "a narrow holding" about only one sort of design defect claim, nor did the Third Circuit express a hint of "ambivalence" about "the scope of § 22." Opp. at 20-21. In advancing these assertions, plaintiffs fixate on a passage that appears after the Third Circuit reached the definitive "*conclusion* that the Vaccine Act preempts *all* design defect claims, including those based in negligence." *Bruesewitz*, 561 F.3d at 248 (emphasis added). In that passage, the Third Circuit buttressed—rather than undermined—its conclusion with the observation that "*[e]ven if* Congress did not intend to prohibit all design defect claims against vaccine manufacturers," it plainly "intended to preempt the specific claim at issue" in

that case. *Id.* at 250 (emphasis added). The Third Circuit underscored that this backup argument was no retreat from the broader holding in a summary section immediately after the "even if" discussion:

> [T]he structure and purpose of [Section 22] make clear that Congress intended to preempt some design defect claims. The legislative history identifies the scope of this preemption, which *encompasses both strict liability and negligent design defect claims.*

Id. at 251 (emphasis added).

Plaintiffs are also incorrect that review should wait, on the chance that other courts will reject the Third Circuit's dismissal of subsequent legislative history. Opp. at 17-22. If anything, the dispute over subsequent legislative history highlights the irreconcilable holdings of the Georgia Supreme Court and the Third Circuit. The Georgia Supreme Court afforded the post-enactment legislative statements nearly dispositive weight. *See* App. 13-15. The Third Circuit, however, consistent with other courts, properly gave the statements no weight. *Bruesewitz*, 561 F.3d at 250. The Third Circuit's conclusion is in keeping with this Court's admonition that such subsequent legislative statements are "a 'hazardous basis for inferring the intent of an earlier' Congress." *Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (quoting *United States v. Price*, 361 U.S. 304, 313 (1960)). Further percolation will not reconcile these divergent approaches to subsequent legislative history or provide a path to reconcile *Bruesewitz* with *Ferrari*.

Congress enacted the Vaccine Act to create a uniform national vaccine policy and to impose uniform standards of responsibility on all vaccine manufacturers in all states. Now, with the Georgia Supreme Court's decision, uniformity is gone. A vaccine manufacturer sued under Georgia law is held to a standard of responsibility for design defect and is subject to litigation that is preempted in any federal court in New Jersey, Pennsylvania, and Delaware. This Court should grant certiorari to resolve this split.

II. LITIGATION AGAINST VACCINE MANUFACTURERS POSES A REAL THREAT TO THE NATION'S VACCINE SUPPLY.

Resolution of the split should not await some future case. The uniform view of the public health community (as expressed in an *amicus* brief submitted by the American Academy of Pediatrics and 10 other physician and public health organizations) is that if the decision below is allowed to stand, it "could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country." AAP Br. at 19. In response, plaintiffs offer bland assurance that the Georgia Supreme Court's rule poses "no plausible national vaccine crisis." Opp. at 23 (capitalization omitted). Because betting against the public health community could have disastrous consequences, the Court should reject plaintiffs' assurance unless it is rooted in solid facts and flawless logic. In fact, plaintiffs' assurance depends on three propositions, all of which are wrong.

Plaintiffs' first argument is that "Petitioners exaggerate the increase in vaccine-related court cases." Opp. at 23 (capitalization omitted). "The recent 'spike,'" they assert, "is nothing more than an illusion created by aggregating data from *four* years into a single bar on the graph." *Id.* at 24 (emphasis in original). But disaggregating that one bar does not erase the spike. Assume, as plaintiffs assert, that it is more appropriate to present the data as if there have been "[o]n average . . . 90 lawsuits per year." *Id.* at 24. If so, the number of vaccine cases filed over the decade are as follows: 13, 6, 4, 1, 5, 2, 90, 90, 90, 90. Pet. at 21. Or, compare the four-year period from 1997 to 2000 against the four-year period from 2001 to 2004: The first period saw 12 cases, the latter period saw over 350 cases. *Id.* However the data is cut, that is a dramatic spike.

Plaintiffs' second argument is that "beyond the supposed uptick in civil filings . . . there is no reason to believe that there will be [a further] unmanageable flood of new vaccine-related litigation in state courts." Opp. at 25. Plaintiffs' main support for this proposition is a chart that they assert indicates that "the number of filings *in the Vaccine Court* in recent years is well within normal parameters." Opp. at 25 (emphasis added). The chart, however, shows that in the last eight years, the Vaccine Court has been flooded by claims linking autism to childhood vaccines (i.e., the very theory advanced by plaintiffs in this case): over 5,500 claims were filed during that time compared to 24 in the previous 14 years – a nearly 230-fold increase. The enormous volume of autism cases led the Vaccine Court to create an unprecedented Omnibus

Autism Proceeding to manage the influx of so many new claims. *See In re Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder*, 2002 WL 31696785 (Fed. Cl. July 3, 2002). Of the autism cases reflected on plaintiffs' chart, over 4,900 still remain in Vaccine Court.

In addition to being wrong, plaintiffs' argument misses the point. Whether *Vaccine Court* filings have remained steady in the years before the Georgia Supreme Court issued its opinion has no bearing on whether plaintiffs will be more likely, going forward, to reject the Vaccine Court's rulings and file civil actions. Every vaccine case has to start in the Vaccine Court. The critical point—and the one plaintiffs fail to answer adequately—is that the Georgia Supreme Court's rule will reduce the Vaccine Court to nothing but a base that plaintiffs touch en route to court.

On this point, plaintiffs' position rests on an implausible scenario: "Even if the Vaccine Court finds no causation"—leaving all 4,900 claimants empty-handed– plaintiffs predict that all those claimants might en masse "conclude that they have had their 'day in court'" and refrain from filing actions in courts, which the Georgia Supreme Court has now declared open for business for design defect claims. Opp. at 28. To predict that a significant proportion of these claimants will opt to proceed to another forum after losing in the Vaccine Court is not "sheer speculation." Opp. at 27. It is common sense, rooted in decades of experience with multiple categories of mass tort cases in U.S. courts. Even if half of the claimants call it quits after a loss in the Vaccine Court, that would leave a flood of over 2,400

claims headed to civil courts—and, if the Georgia Supreme Court rule prevails, to trial on a design defect theory.

Finally, plaintiffs argue that the Court should be unconcerned by any potential deluge, because "Congress expressly *preserved* the ability of" plaintiffs to sue in court on claims like these. Opp. at 25 (emphasis in original). But that is the very question presented by this case—one that should be reviewed and considered by this Court. If plaintiffs are wrong—and Congress in fact intended to block the very sorts of design defect claims that triggered the vaccine crisis in the first place—then the prospect of an imminent deluge poses the very threat to public health that Congress sought to prevent.

III. THIS COURT HAS JURISDICTION TO REVIEW THE GEORGIA SUPREME COURT'S DECISION.

As the Petition explains, the Georgia Supreme Court's judgment is reviewable under the fourth category of cases identified in *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 482-83 (1975). *See* Pet. at 1-2. This case satisfies all three prongs required by that category. Plaintiffs concede the first prong is met, but they contest the other two. They are wrong.

Prong two requires a showing that "reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state proceedings still to come." *Cox*, 420 U.S. at 482-83. In other words, in order to establish jurisdiction as to any

"relevant cause of action," Petitioners must demonstrate that the "relevant cause of action": (1) survives to proceed to trial under the Georgia Supreme Court's ruling; but (2) would be precluded if Petitioners were to prevail in this Court.

Here, plaintiffs have asserted two distinct design defect causes of action. First, plaintiffs pled a strict liability design defect claim. App. 1. Petitioners argued that this claim is preempted. The Georgia Supreme Court rejected that argument, which means that there *will* be further litigation on the claim, unless this Court intervenes. App. 18. If Petitioners persuade this Court that this claim is preempted, there will be no further litigation on the claim. Plaintiffs do not dispute this.

Second, plaintiffs pled a separate, and wholly distinct, negligent design defect claim. App. 1. This claim is in the same procedural posture as the strict liability claim. Every word of the previous paragraph applies with equal force to this second design defect claim. Plaintiffs do not dispute this, either.

Plaintiffs nevertheless insist that there is no jurisdiction, as to either claim. They assert that it is conceivable that the reversal of the decision below might "not completely preclude [plaintiffs'] design defect claim, but merely dictate [plaintiffs'] burden of proof." Opp. at 14. Specifically, they hypothesize that the Court may ultimately accept the preemption defense as to claim one (strict liability) but reject the preemption defense as to claim two (negligent design). *Id.* at 13-14. Such a split decision is a legal impossibility, for there is no way to read Section 22

to distinguish one sort of design defect claim from another—and no court, on either side of the divide, ever has.

In any event, when plaintiffs refer to different "burden[s] of proof," what they actually mean is that the two alternative claims have different elements. Their jurisdictional argument pretends that this case presents a choice between two evidentiary routes toward proving a singular "design defect claim"—a solitary "underlying cause of action" that could survive in part even if this Court reverses the Georgia Supreme Court. Opp. at 14. Not so. The two claims are distinct causes of action and plaintiffs pleaded them as such. App. 1. When each of the "relevant cause[s] of action" is considered separately, as *Cox* requires, 420 U.S. at 482-83, this Court faces a binary choice: to allow each "relevant cause of action" to proceed (as the Georgia Supreme Court directed) or to reverse and preclude the "relevant cause of action" in its entirety (as Petitioners advocate and as every court outside Georgia has held). If, as Petitioners have demonstrated, the Court would have jurisdiction as to each claim if presented alone, it does not lose jurisdiction just because both claims are in the same case.

That binary choice distinguishes this case from *Nike, Inc. v. Kasky*, 539 U.S. 654 (2003). In *Kasky*, the question was whether Nike's allegedly false statements were protected by the First Amendment. *Id.* at 657. As Justice Stevens's concurrence explains, the Court had to dismiss the case for lack of jurisdiction because there were a number of scenarios in which the Court could reverse the state court without finally disposing of the First

Amendment defense to the plaintiff's claims. *Id.* at 660 (Stevens, J., concurring). That is not the situation here. The only question presented in this case is whether the Vaccine Act categorically preempts all design defect claims. This Court will have no choice but to answer this question definitively if it reviews the Georgia Supreme Court's judgment.

As to prong three, for all the reasons recited above and in the Petition (Pet. at 19-26), and in the *amicus* briefs (AAP Br. at 18-21), plaintiffs are incorrect in disputing that "refusal immediately to review the state court decision might seriously erode federal policy." *Cox Broad. Corp.*, 420 U.S. at 483. The danger is created by the very existence of the Georgia Supreme Court opinion, which will open the floodgates to the litigation deluge that spurred Congress to action in the first place.

Plaintiffs' main argument about this third prong—that "[t]his Court is . . . likely" to address the preemption question "in a future case" (Opp. at 14)—is not at all responsive either to the federal policy or to the emergency. If a flood occurs, later will be too late. In this regard, this case is analogous to *Belknap, Inc. v. Hale*, where this Court found that it had jurisdiction to review the state court judgment because to allow proceedings to continue in state court "without resolving the preemption issue would involve the serious risk of eroding the federal statutory policy of 'requiring the subject matter of respondents' cause to be heard by the . . . [National Labor Relations] Board, not by the state courts.'" 463 U.S. 491, 497 n.5 (1983) (quoting *Cox Broad. Corp.*, 420 U.S. at 483).

Here, the split between the courts can be reduced to a similar forum-related question: Did Congress intend for the Vaccine Court to be the only forum available to claimants alleging that their vaccine-related injury is attributable to the FDA-approved design of the vaccine—or is a civil court also an appropriate forum? Requiring manufacturers to litigate the safety of FDA-approved vaccine designs in courts across the country involves a serious risk of eroding the federal statutory policy to "reduce and stabilize litigation costs" by removing such claims from civil litigation. *Bruesewitz*, 561 F.3d at 249. The determination of this critical threshold issue should not be delayed.

CONCLUSION

The petition for a writ of certiorari should be granted.

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No. 08-1120

In the Supreme Court of the United States

AMERICAN HOME PRODUCTS CORPORATION, D/B/A WYETH, ET AL., PETITIONERS

v.

MARCELO A. FERRARI, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF GEORGIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

The National Childhood Vaccine Injury Act of 1986 provides that "[n]o vaccine manufacturer shall be liable in a civil action" for any injury that "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(1). The question presented is whether that provision preempts state law claims against a vaccine manufacturer based on alleged defects in the design of a vaccine subject to the Act.

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In the Supreme Court of the United States

No. 08-1120

AMERICAN HOME PRODUCTS CORPORATION, D/B/A WYETH, ET AL., PETITIONERS

v.

MARCELO A. FERRARI, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF GEORGIA

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, because of mootness concerns, the petition for a writ of certiorari should be held pending the disposition of *Bruesewitz* v. *Wyeth, Inc.*, petition for cert. pending, No. 09-152 (filed Aug. 4, 2009), or be denied. The Court should grant the petition for a writ of certiorari in *Bruesewitz*, which presents the same question.

STATEMENT

Respondents brought this action in Georgia state court against petitioners, the manufacturers of vaccines administered to respondents' son. The suit alleged that the vaccines caused respondents' son to suffer neurological injuries because they contained the preservative thimerosal. The trial court dismissed respondents' de-

sign defect claims as preempted by the National Childhood Vaccine Injury Act of 1986 (Vaccine Act or Act), Pub. L. No. 99-660, Tit. III, 100 Stat. 3755 (42 U.S.C. 300aa-1 *et seq.*). The Supreme Court of Georgia ultimately reinstated the claims.

1. "[T]wo overriding concerns" prompted the Act: "the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of [a tort-based] approach to compensating those who have been damaged by a vaccine," and "the instability and unpredictability of the childhood vaccine market" due to vaccine manufacturers' fear of tort liability. H.R. Rep. No. 908, 99th Cong., 2d Sess. 7 (1986) (*1986 Report*). Accordingly, the Act is designed to encourage "development and distribution of vaccines that will further enhance the public health" (particularly those recommended for routine administration to children), and to compensate individuals injured by such vaccines by means other than tort law. *Ibid.*

The Act does so by, *inter alia*, establishing a National Vaccine Advisory Committee, funding vaccine research, promoting dissemination of information on vaccines, and collecting data on adverse events related to vaccine administration. 42 U.S.C. 300aa-5, 300aa-6(b), 300aa-25, 300aa-26, 300aa-28. Compensation for injuries comes primarily from the National Vaccine Injury Compensation Program, which offers "no-fault" monetary awards to individuals who suffer injuries causally associated with particular childhood vaccines. See *Shalala* v. *Whitecotton*, 514 U.S. 268 (1995). The program is funded by Congressional appropriations and an excise tax on each vaccine dose. 42 U.S.C. 300aa-10 to 300aa-19; 26 U.S.C. 4131.

To receive compensation for a vaccine-related injury or death, the injured party (or his legal representative) must file a petition in the Court of Federal Claims (CFC), naming the Secretary of Health and Human Services (Secretary) as respondent. 42 U.S.C. 300aa-11(a), 300aa-12(a) and (b). The claimant need show by a preponderance of the evidence only that he received a vaccine listed on the "Vaccine Injury Table"[1] and suffered a corresponding listed injury, or that a listed vaccine in fact caused or significantly aggravated any injury. 42 U.S.C. 300aa-11(c), 300aa-13(a). The claimant does not need to establish any defect in the vaccine or fault on the part of the manufacturer.

A petition for compensation is initially heard by a special master appointed by the CFC, whose decision is reviewable by the CFC, and in turn by the Federal Circuit. 42 U.S.C. 300aa-12(e)-(f). Awards cover medical costs, lost earning capacity, and pain and suffering. 42 U.S.C. 300aa-15(a). To ensure representation, the Compensation Program awards reasonable attorneys' fees even if there is no award to the claimant, provided the petition was brought in good faith on a reasonable basis. 42 U.S.C. 300aa-15(e).

The Act forbids a claimant from resorting immediately to a civil action for damages against the vaccine's manufacturer. Rather, he must first file a petition under the no-fault scheme and seek a judgment from the CFC. 42 U.S.C. 300aa-11(a)(2)-(3). If the claimant

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[1] The Secretary maintains the Table at 42 C.F.R. 100.3. To be included on the Table, a category of vaccine must be "recommended for routine administration to children" by the Centers for Disease Control and Prevention, 42 U.S.C. 300aa-14(e)(2) and (2)(A), and Congress must fund awards by subjecting the category of vaccine to the excise tax, Act of Aug. 10, 1993, Pub. L. No. 103-66, § 13632(a)(3), 107 Stat. 646.

elects to reject that judgment (and any award), or withdraws his petition after the special master or CFC fails to render a judgment within specified time periods, then the Act permits him to bring a civil action against the manufacturer. 42 U.S.C. 300aa-11(a)(2)(A), 300aa-21(a)-(b).

Such actions are governed by state law, subject to the Act's specific limitations. 42 U.S.C. 300aa-22. Among these limitations is the provision at issue here:

> No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. 300aa-22(b)(1).

2. Relative to the tens of millions of childhood vaccine doses administered annually, the number of petitions in the CFC is small—reflecting the extraordinary safety of the covered vaccines. Since the first few years of the Compensation Program (which saw several thousand claims for injuries that pre-dated the Act), there typically have been 100 to 200 ordinary claims filed annually. Approximately one third of such claims are ultimately compensated, with the average award exceeding $750,000. See Health Res. & Servs. Admin., Dep't of Health & Human Servs., *National Vaccine Injury Compensation Program Post-1988 Statistics Report* (Dec. 2, 2009) <http://www.hrsa.gov/vaccinecompensation/statistics_report.htm> (*Statistics Report*).

Not counted among these ordinary claims are more than 5600 petitions asserting a causal link between

childhood vaccines containing thimerosal (as well as certain measles-mumps-rubella (MMR) vaccines) and neurological damage; approximately 5000 such petitions remain pending and have been consolidated before the CFC in the Omnibus Autism Proceeding (OAP). See *Statistics Report*. Six "test cases" were identified in the OAP to present two "general theor[ies] of causation." See *Cedillo* v. *Secretary of HHS*, No. 98-916V, 2009 WL 331968, at *9-10, *11 n.16 (Fed. Cl. Feb. 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), appeal pending, No. 2010-5004 (Fed. Cir. filed Oct. 7, 2009). In the test cases presenting the first theory, special masters ruled that vaccines did not cause the claimants' injuries, and the CFC has affirmed those decisions. *Ibid.*; *Hazlehurst* v. *Secretary of HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009), aff'd, 88 Fed.Cl. 473 (2009), appeal pending, No. 2009-5128 (Fed. Cir. filed Sept. 21, 2009); *Snyder* v. *Secretary of HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009), aff'd, 88 Fed. Cl. 706 (2009). In the test cases presenting the second theory of causation, the masters have held evidentiary hearings and received post-hearing briefing, and decisions are expected early this year. The CFC must decide each case in the omnibus proceeding individually (see 42 U.S.C. 300aa-12(d)(3), 300aa-13(a)), but the resolution of the test cases is expected to lead to efficient resolution of most of the remaining cases.

3. Respondents filed this action in state court against several vaccine manufacturers, including two of the petitioners here. Pet. App. 33-35; Compl. 2-3. The complaint alleged that respondents' son had suffered neurological injuries from exposure to vaccines produced by petitioners and approved by the Food and Drug Administration (FDA) that contained the preser-

vative thimerosal. Pet. App. 36. Petitioners moved for summary judgment, contending that respondents' claims are preempted by Section 22(b)(1). See *id.* at 34-37. As relevant here, the trial court granted that motion to the extent respondents' claims were based on the alleged design defect of using thimerosal. *Id.* at 49.

The Supreme Court of Georgia reinstated respondents' claims. The Georgia court construed "unavoidable" in Section 22(b)(1) by looking to the *1986 Report*, which commented on the text that became Section 22(b)(1). Pet. App. 7. That report states that Section 22(b)(1) was modeled on Restatement (Second) of Torts § 402A cmt. k (1965) (Comment k), which protects the seller of "unavoidably unsafe" products. Pet. App. 11 (quoting *1986 Report* 26 (quoting Comment k)). The Georgia court read the reference to Comment k as showing Congress's intent not to bar all design defect claims against vaccine manufacturers, but instead to allow juries to undertake a case-by-case analysis of whether a safer vaccine design was available. *Id.* at 7-10.

Pointing to the phrase "'if the [vaccine-related] injury or death resulted from side effects that were unavoidable,'" the court observed that "[t]he conditional nature" of this language demonstrated that Congress contemplated "the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable." Pet. App. 10 (first brackets in original) (quoting 42 U.S.C. 300aa 22(b)(1)). The court also relied on language in a post-enactment 1987 congressional committee report on legislation that funded awards under the Compensation Program. *Id.* at 13-14. In the court's view, that report offered a "strikingly clear and emphatic" indication that Section 22(b)(1) was not a categorical bar to design defect claims. *Id.* at 14.

4. Six months after petitioners sought review in this Court, respondents voluntarily dismissed their claims in state court without prejudice. Resp. Supp. Br. App. 1a-2a.

DISCUSSION

The Supreme Court of Georgia erred in holding that the Vaccine Act allows juries to resolve, on a case-by-case basis, claims that a vaccine approved by the FDA could have been designed in a way that would not have injured the plaintiff. That misunderstands the text of Section 22(b)(1), conflicts with the Act's legislative history, and frustrates Congress's intent to stabilize the market for vaccines critical to children's health. Congress intended through Section 22(b)(1) to exempt vaccine manufacturers from design-defect liability, while still offering, through other provisions of the Act, compensation to the injured and inducements to devise even safer vaccines.

The Georgia court's decision squarely conflicts with *Bruesewitz* v. *Wyeth Inc.*, 561 F.3d 233, 242-243 (3d Cir. 2009), petition for cert. pending, No. 09-152 (filed Aug. 4, 2009). Moreover, the question presented is pressing. While it remains unsettled, manufacturers' uncertainty about their potential liability for design defects may harm the public health by deterring their development and production of vaccines. At the same time, thousands of claimants in the OAP do not know whether they may seek civil tort remedies. The issue therefore warrants this Court's review. Because of a mootness question in this case, however, the Court should grant the petition in *Bruesewitz*, which presents the same question.

I. THE GEORGIA SUPREME COURT MISINTERPRETED THE VACCINE ACT'S PREEMPTIVE REACH

Section 22(b)(1) expressly preempts state law. See, *e.g.*, Pet. App. 4; *Bruesewitz*, 561 F.3d at 242-243. The task therefore is to "identify the domain expressly preempted by that language." *Medtronic* v. *Lohr*, 518 U.S. 470, 484 (1996) (internal quotation marks and citation omitted). The preemptive reach of Section 22(b)(1) turns on what Congress intended to convey by invoking the term of art "unavoidable." The Georgia Supreme Court concluded that the term is "most consistent with" a case-by-case approach, under which a claim is not preempted if a plaintiff can show that an injury from side effects was "avoidable by a feasible alternative design." Pet. App. 10-11. By contrast, petitioners contend that "unavoidable" conveys Congress's blanket determinations that childhood vaccines, although offering immense social benefits, must be "deemed to be 'unavoidably unsafe' because they carry an inherent risk of injury"—and that such products, in accordance with common law principles, should not expose their manufacturers to liability for design defects. Pet. 30. Petitioners' reading of Section 22(b)(1) is correct.[2]

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[2] Because Section 22(b)(1) is an *express preemption provision*, *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1193 (2009), which concerned implied preemption, is of limited relevance. Moreover, the precise question in *Levine* was whether federal drug labeling law impliedly preempted the plaintiff's claim that a drug should have borne more stringent warnings than approved by FDA. The Act here speaks directly to vaccine labeling by providing that a vaccine that complies with all FDA requirements "shall be presumed to be accompanied by proper directions and warnings." 42 U.S.C. 300aa-22(b)(2).

1. Pointing to the phrase "if the injury or death resulted from side effects that were unavoidable" (42 U.S.C. 300aa-22(b)(1)), the Georgia court concluded that "[t]he conditional nature of this clause contemplates the occurrence of side effects which are avoidable, and for which a vaccine manufacturer may be civilly liable." Pet. App. 10. From that premise, the court reasoned that claims based on avoidable design defects are not preempted, because if Congress had intended to bar all design defect liability, it could have said so more clearly. *Id.* at 10-11.

That approach to the statutory language is incorrect. "[I]t is always possible to construct through hindsight an alternate structure for a statute with alternative wording that would render it more clear." *Bruesewitz*, 561 F.3d at 246. The more relevant question is what the best reading of the actual language is. Here, that language indicates which side effects Congress thought avoidable and which it did not. The modifying clause beginning "even though" explicates the universe of "avoidable" side effects—*i.e.*, those caused by manufacturing defects or improper labeling. Side effects alleged to inhere in the vaccine's FDA-approved design are excluded from that list of "avoidable" side effects, for which civil liability is appropriate. The result is that Section 22(b)(1) bars one theory of liability (design defect), while leaving in place two others (manufacturing and labeling defects), subject to other limitations in the Act.

2. The Act's legislative history supports this understanding. The *1986 Report* explains (at 25-26) that "unavoidable" was drawn from Comment k, which concerns "*[u]navoidably unsafe products.*" Restatement (Second) of Torts § 402A cmt. k at 353 (1965) (caption).

Comment k recognizes that "[t]here are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," and offers a vaccine as a prototypical example. *Ibid.* Under Comment k, such a product is "not defective" as a matter of law, and the seller cannot be held liable for the consequences of its use as long as it was "properly prepared and marketed" and accompanied by "proper warning." *Id.* at 354. Section 22(b)(1) codifies that rule.

The *1986 Report* states that the Committee invoked Comment k "because it intends that the principle in Comment K regarding 'unavoidably unsafe' products * * * apply to the vaccines covered in the bill and that such products not be the subject of liability in the tort system." *1986 Report* 26. In other words, vaccines covered by the Compensation Program would be deemed "unavoidably unsafe products," and thus not subject to design-defect claims. The *1986 Report* further explains:

> Given the existence of the [no-fault] compensation system in this bill, * * * [v]accine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

Ibid.

The Georgia Supreme Court read this language as merely a prediction that vaccine claimants alleging design defects would find the new compensation system "appealing," despite being "authorized to [resort to] the

tort system." Pet. App. 13. That misunderstands the Report in two ways. First, the Report does not say that claimants are "authorized" to pursue tort remedies; to the contrary, it states that such claimants "should * * * *not*" "pursue recompense in * * * the tort system." *1986 Report* 26 (emphasis added). Second, the Georgia court's reading ignores the essential point of the quoted passage, which is that the Act treats design defect claims differently from claims based on manufacturing and labeling defects. Only the latter two theories can be pursued in the tort system.

To support its interpretation of Section 22(b)(1), the Georgia court also relied on language in a 1987 committee report that post-dated passage of the Act. Pet. App. 14 (citing H.R. Rep. No. 391, 100th Cong., 1st Sess. 691 (1987) (*1987 Report*)). According to that report, the codification of Comment k "was not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe." *1987 Report* 691. The report further stated that "[t]his question is left to the courts to determine in accordance with applicable law." *Ibid.*

The *1987 Report* is not persuasive authority for interpreting the Act as passed in 1986. It was prepared after Section 22(b)(1) became law. As this Court explained in *District of Columbia* v. *Heller*, 128 S. Ct. 2783 (2008), statements by those who drafted or voted for a law are relevant to statutory interpretation "not because they reflect the general understanding of the disputed terms, but because the legislators who heard or read those statements presumably voted with that understanding." *Id.* at 2805. Conversely, statements made after enactment "could have had no effect on the congressional vote." *Ibid.* To be sure, Section 22(b)(1) did not become

effective until the Compensation Program was funded by the appropriations that were the subject of the *1987 Report*. See Br. in Opp. 20. But Members of Congress who voted for the Compensation Program and the associated preemption provision in 1986 did so with the understanding not of some later document, but rather of the *1986 Report* that vaccine design should "not be the subject of liability in the tort system." *1986 Report* 26.[3]

3. Preemption of all design defect claims flows from the Act's structure and purpose as well. Fear of "instability and unpredictability of the childhood vaccine market" due to the threat of large tort liability was an "overriding concern[]" that prompted the Act. *1986 Report* 7; see also *Schafer* v. *American Cyanamid Co.*, 20 F.3d 1, 4 (1st Cir. 1994) (Breyer, C.J.) ("[A]n important federal purpose of the Act is to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market.").

The Act would do little to address this problem if it permitted any vaccine claimant disappointed with the CFC's judgment to seek all the customary product liability tort remedies in a civil action. Indeed, consistent with Comment k's statement of the law, no or few States

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[3] The *1987 Report* also states (at 691) that when the House Committee on Energy and Commerce considered the original act in 1986, it rejected an amendment providing that "a manufacturer's failure to develop a safer vaccine was not grounds for liability." See House Energy & Commerce Comm., Markup Hearing on H.R. 5546, at 46-54 (Sept. 18, 1986) (rejecting amendment). The proceedings within a single committee's markup session are likewise not an authoritative guide to what Congress understood and intended in passing a bill. Rather, "the authoritative source for finding the Legislature's intent lies in the Committee Reports on the bill." *Eldred* v. *Ashcroft*, 537 U.S. 186, 210 n.16 (2003) (quoting *Garcia* v. *United States*, 469 U.S. 70, 76 (1984)).

in 1986 would have imposed tort liability on a vaccine manufacturer absent a showing by the plaintiff of a safer alternative design. Thus, on respondents' view of the Act, Congress intended to preempt liability only for conduct that state law probably would not have held tortious in the first place. That result does little to address the burden of litigation or the threat of large and unpredictable tort judgments against vaccine manufacturers. At most, awards under the Compensation Program might satisfy or dissuade some number of claimants, somewhat reducing the number of potential civil tort plaintiffs.

Other parts of the Act also indicate that Congress intended more comprehensive and farther-reaching reform of the vaccine tort system than respondents suggest. The Act achieves the principal goals of product liability design defect law—compensation for the injured and incentives for safer products, see *Wyeth* v. *Levine*, 129 S. Ct. 1187, 1202 (2009)—by other means.

The Compensation Program provides relief through a system that is simpler and more generous than the tort system. See *Shalala* v. *Whitecotton*, 514 U.S. 268, 269 (1995); *1986 Report* 6 ("[F]or the relatively few who are injured by vaccines * * * the opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered."). Significantly, the Vaccine Injury Table controls the scope of the Act for both compensation and preemption purposes, ensuring that compensation is potentially available whenever tort remedies are preempted.[1]

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[1] The Compensation Program requires proof that the injured party received a vaccine on the Table. See 42 U.S.C. 300aa-11(c)(1)(A), 300aa-13(a)(1)(A). As for preemption, Section 22(b)(1) preempts only claims for "vaccine-related injury or death," which is by definition limi-

Safer vaccines are promoted through a rigorous FDA approval process. New childhood vaccines in particular are put through some of the most exhaustive examinations and largest clinical trials of any FDA-approved product. For example, development of new vaccines for rotavirus gastroenteritis began in the early 1980s and, after clinical trials involving more than 130,000 participants, culminated in FDA approval in 2006 and 2007 of the vaccines. See Stanley A. Plotkin et al., *Vaccines* 719-720 (5th ed. 2008); Roger I. Glass & Umesh D. Parashar, *The Promise of New Rotavirus Vaccines*, 354 New Eng. J. Med. 75, 76 (2006). Each type of vaccine subject to the Act has been approved by the FDA as a biological product following such an extensive process, or is currently undergoing FDA-regulated clinical trials. See 42 U.S.C. 262(a).[5]

Vaccine safety and innovation are also encouraged through direct government funding of research. Government-wide statistics are not readily available, but the National Institutes of Health (NIH) alone reports funding about $1.5 billion of vaccine research per year. See NIH, Dep't of Health & Human Servs., *Estimates of Funding for Various Research, Condition, and Disease Categories* (rev. May 7, 2009) <http://report.nih.gov/rcdc/categories>. In addition, expert government agencies (such as the Centers for Disease Control and Prevention (CDC)) and nongovernmental organizations (such as the American Academy of Pediatrics) have sig-

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ted to injuries "associated with one or more of the vaccines set forth in the Vaccine Injury Table," 42 U.S.C. 300aa-33(5).

[5] Conceivably some vaccines administered abroad to federal employees and their dependents would be covered by the Act, see 42 U.S.C. 300aa-11(c)(1)(B)(i)(II), but not subject to FDA regulation.

nificant influence over the vaccines that are administered to children.

The Act itself ensures continuous monitoring of vaccine safety by requiring that both vaccine manufacturers and health care providers report side effects (and other contraindicating reactions) to the Secretary through the Vaccine Adverse Event Reporting System. 42 U.S.C. 300aa-25(b); see http://vaers.hhs.gov. Mandatory reporting by health care providers of adverse events makes the reporting system for vaccines even more comprehensive than parallel systems applicable to drugs and non-vaccine biological products. Compare 42 U.S.C. 300aa-25(b) (vaccines), with 21 C.F.R. 600.80 (biological products generally), 21 U.S.C. 355(k)(1) (drugs), and 21 C.F.R. 314.80 (drugs).

Routinely administered vaccines are products for which the design trade-offs between safety and efficacy affect not only individual recipients, but also the entire society, which benefits from vaccines potent enough to ensure that a disease is contained or (as with smallpox) eradicated. See *Schafer*, 20 F.3d at 4. The tort system—in which juries may pay little heed to this social cost/benefit calculus, see *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008)—is poorly equipped to encourage optimally safe and effective vaccines. That is why Congress recognized through the Act that expert regulators should control design decisions, with relief available under the Compensation Program.

II. THE SPLIT BETWEEN THE GEORGIA SUPREME COURT AND THE THIRD CIRCUIT MERITS THIS COURT'S ATTENTION

A. The Georgia Supreme Court's decision directly conflicts with the Third Circuit's decision in *Bruesewitz*,

which held that Section 22(b)(1) preempts all design defect claims. 561 F.3d at 235, 251, 255.

Bruesewitz concerns a child who experienced seizures after her third dose of a diphtheria-tetanus-pertussis (DTP) vaccine. She ultimately suffered residual seizure disorder and developmental delay. Her parents pursued a timely but unsuccessful petition for compensation in the CFC, *Bruesewitz* v. *Secretary of HHS*, No. 09-266V, 2002 WL 31965744 (Fed. Cl. Dec. 20, 2002), and rejected the CFC's judgment pursuant to 42 U.S.C. 300aa-21(a)(1). They then sued the manufacturer of the DTP vaccine in Pennsylvania state court, alleging (as relevant here) that toxins inherent in the vaccine's design caused their daughter's injuries. The manufacturer removed the case on the basis of diversity of citizenship, and the district court granted summary judgment for the manufacturer, holding that the Act preempted the plaintiffs' design-defect claims. See *Bruesewitz*, 561 F.3d at 236-238.

The Third Circuit affirmed. It began with the Act's text, which it read to preclude tort litigation over at least some design defect claims. *Bruesewitz*, 561 F.3d at 245. The court noted that Section 22(b)(1) "primarily relates to design defect claims," because the other types of products liability claims (*i.e.*, for manufacturing or labeling defects) are dealt with in the "subordinate clause introduced by 'even though.'" *Ibid.* The Third Circuit rejected the Georgia court's textual analysis "because it does not bar any design defect claims"—that is, "[i]f we interpret the Vaccine Act to allow case-by-case analysis of whether particular vaccine side effects are avoidable, every design defect claim is subject to evaluation by a court." *Id.* at 246. The Third Circuit went on to conclude, based on legislative history, that

the Act preempts all design defect claims irrespective of whether they sound in negligence or strict liability. *Id.* at 247-250.

Bruesewitz expressly rejects the reasoning of the Georgia Supreme Court. See *Brueswitz*, 561 F.3d at 248 ("In our view, the [1986] Report supports the conclusion that the Vaccine Act preempts all design defect claims."); *id.* at 246 ("[T]he *Ferrari* Court's construction [of Section 22(b)(1)] is contrary to the structure of the Act because it does not bar any design defect claims."); *id.* at 250 ("[W]e have no basis to conclude that the [1987] Report is an accurate reflection of * * * the motivations underlying Congress's enactment of the Vaccine Act in 1986."). The conflict is thus squarely presented.[6]

B. The question presented is already informed by thorough analyses from several trial and appellate courts, and further attention from lower courts would contribute little to the debate. The issue has nationwide significance, and a decision from this Court would foster sound judicial administration and advance the public health, for three reasons in particular.

1. The question presented is important to more than 5000 claimants in the OAP currently pending before the CFC. To date, those claimants have been unsuccessful.

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[6] Respondents would avoid the conflict by confining *Bruesewitz*'s holding to preemption of DTP design-defect claims, based on the Third Circuit's observation (561 F.3d at 250) that Congress was particularly concerned with DTP-related claims in passing the Act. See Br. in Opp. 21. But the distinction respondents perceive would dismiss nearly all of the Third Circuit's analysis as dicta, and that distinction has no basis in the law. The Act draws only one relevant distinction: between vaccines that are on the Table and those that are not. See, *e.g.*, 42 U.S.C. 300aa-11(c)(1)(A) and 300aa-33(5).

If that remains the case, many may elect to pursue tort remedies against manufacturers. Efficient judicial administration counsels early resolution of threshold legal issues likely to arise in those suits.

2. Fears of design defect liability could stall vaccine innovation while the law remains unsettled. Routine childhood vaccines typically have such a low rate of unavoidable serious side effects (sometimes numbering in the single digits per million doses) that they may not be discovered even in massive clinical trials. Public health would be undermined if manufacturers chose not to pursue research and development of new vaccines for fear of unknown exposure to liability. Current research offers several examples of vaccine development strategies that promise significant advantages in safety and efficacy, but that may result in unknown rare side effects:

- *Adjuvants.* Currently, many childhood vaccines must be administered in multiple doses to confer lasting immunity. Adding certain compounds (known as adjuvants) to the vaccine may so improve the immune response that fewer doses are needed. See, *e.g.*, P. Helena Mäkelä, *Vaccines, Coming of Age After 200 Years*, 24 FEMS Microbiology Rev. 9, 14-15 (2000) (*Vaccines, Coming of Age*). This strategy would avoid underimmunization due to missed doses and permit faster responses to epidemics. But conceivably the adjudvant might provoke a rare side effect—one the Georgia court might label "avoidable" because the vaccine could have been administered without the adjuvant.

- *Cell-based influenza vaccine.* Currently, many influenza vaccines—including most for seasonal

influenza—are produced in chicken eggs, a process that takes several months. *Vaccines* 266. Novel and much more rapid cell-based approaches to producing influenza vaccines are under development. See *Ibid.*; Nat'l Inst. of Allergy & Infectious Diseases, Dep't of Health & Human Servs., *The Jordan Report: Accelerated Development of Vaccines 2007*, App. A at 132 (May 2007). The ability to begin production closer to the flu season would improve the accuracy of predicting which strains will be dominant in a given year, and would allow manufacturers to respond to late-appearing strains. See Manon M.J. Cox, *Cell-Based Protein Vaccines for Influenza*, 7 Current Opinion in Molecular Therapeutics 24, 24-26 (2005). Faster production would also allow swifter response to pandemic flu outbreaks. See *id.* at 26; Homeland Sec. Council, *National Strategy for Pandemic Influenza: Implementation Plan* 105 n.16 (May 2006). But as with any new technique, cell-based approaches to producing vaccines could have side effects—and the Georgia court could label these side effects "avoidable" because the vaccines could instead have been produced using chicken eggs.

- *DNA vaccines.* Most vaccines work by introducing a harmless substance (such as a partial or inactivated virus or toxin) that teaches the body to recognize the molecular characteristics of a pathogen, so that the immune system will react swiftly in response to a true threat. See CDC, Dep't of Health & Human Servs., *How Vaccines Prevent Disease* (last modified Aug. 7, 2009) <http://www.cdc.gov/vaccines/vac-gen/howvpd.

htm>. DNA vaccines operate by introducing DNA sequences that prompt the body itself to make a small amount of the teaching substance. See *Vaccines, Coming of Age* 15-16. The technique promises new vaccines and more effective versions of existing vaccines. See *Jordan Report* App. A (listing DNA vaccines under development). But any side effects could be "avoidable" on the Georgia court's view if an injured party could point to the older version of the vaccine as an alternative.

3. Withdrawal of a manufacturer from the vaccine market for fear of design defect liability could have substantial public health consequences. As noted above, the Congress that passed the Act was concerned about just such instability and unpredictability in the vaccine market. Congress anticipated that the Act would give manufacturers "a better sense of their potential litigation obligations" and that, as a result, "a more stable childhood vaccine market [would] evolve," *1986 Report* 7. But as amici the American Academy of Pediatrics et al. stress (Br. 19-20), vaccines still are produced by very few manufacturers.

The Georgia court's decision could affect the existing balance. To be sure, predicting what a vaccine manufacturer might do in the future is inherently speculative. Manufacturers' potential liability for cases like this one and *Bruesewitz* lies principally in past events. The DTP vaccine that allegedly caused the *Bruesewitz* plaintiffs' daughter's injuries is no longer administered to children in the United States; similarly, the preservative thimerosal, which allegedly caused respondents' son's injuries, is no longer used in vaccines routinely administered to

infants and young children in the United States.[7] But the withdrawal in the future of even one of the handful of manufacturers producing vaccines could lead to a vaccine shortage. That shortage would not only risk disease for those left unvaccinated, but create conditions in which disease could run freely throughout the community. That is because vaccines are administered not only to immunize individuals, but also "to reduce transmission of infection and thereby to prevent disease even in non-vaccinated individuals, thus to protect communities." *Vaccines* 1573.[8]

III. *BRUESEWITZ* IS THE APPROPRIATE VEHICLE FOR RESOLUTION OF THE QUESTION PRESENTED

Respondents' voluntary dismissal in state court raises a substantial question concerning mootness that did not exist when this Court called for this Office's views. See Resp. Supp. Br. 1-2; Pet. Supp. Br. 3-5. Petitioners are correct that the Court has occasionally found a case to remain live notwithstanding post-petition developments that seemingly ended the controversy be-

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[7] The exceptions to this are certain influenza vaccines preserved with thimerosal, and certain other vaccines containing trace amounts of thimerosal. See FDA, Dep't of Health & Human Servs., *Thimerosal in Vaccines* tbl. 1 (last modified Nov. 6, 2009) <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm>.

[8] Congress and the Secretary have demonstrated a similar concern in responding to threats like the H1N1 influenza pandemic. See 42 U.S.C. 247d-6d (added by Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-146, Div. C, § 2, 119 Stat. 2818) (barring liability for designated vaccines and other countermeasures, except for cases of "willful misconduct"); 74 Fed. Reg. 30,294 (2009) (designating H1N1 vaccines—which, unlike the trivalent seasonal influenza vaccine, are not subject to the Vaccine Act—for such protection).

tween the parties. But none of the cases the parties cite from this Court's mootness jurisprudence squarely addresses the precise situation here. See *City News & Novelty, Inc.* v. *City of Waukesha*, 531 U.S. 278, 282-286 (2001); *City of Erie* v. *Pap's A.M.*, 529 U.S. 277, 288 (2000); *Deakins* v. *Monaghan*, 484 U.S. 193, 199-201 (1988). And no party suggests the threshold mootness question is independently certworthy.

Because *Bruesewitz* is a suitable alternative vehicle, the Court can address the important legal question here while avoiding the mootness issue. *Bruesewitz* appears jurisdictionally sound,[9] and the questions presented in that case and this one are materially identical. The claims in *Bruesewitz* (which involve administration of a particular DTP vaccine) are not representative of the claims in the OAP (which involve administration of MMR and thimerosal-containing vaccines), but that difference is legally immaterial. Organizations aligned with OAP claimants would likely present their views as

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[9] The *Bruesewitz* plaintiffs challenged the defendant manufacturer's removal of the case to federal court on diversity of citizenship grounds, asserting that all parties were Pennsylvania citizens. Applying the Third Circuit's multi-factor "center of corporate activities" test to decide the manufacturer's "principal place of business," the district court concluded that the manufacturer was a citizen of New Jersey (and Delaware, where it is incorporated), and thus diverse. *Bruesewitz* v. *Wyeth, Inc.*, No. 05-5994, Docket entry No. 13 (E.D. Pa. Mar. 27, 2006).

This Court's decision in *Hertz Corp.* v. *Friend*, No. 08-1107 (argued Nov. 10, 2009)—which concerns the test for deciding a corporation's "principal place of business" under 28 U.S.C. 1332(c)(1)—is unlikely to nullify the district court's jurisdiction in *Bruesewitz*. The manufacturer (whose executive offices are in New Jersey) would certainly be a citizen of New Jersey under the *Hertz* petitioner's proposed "headquarters" test, and likely would also be a citizen of that State under the *Hertz* respondent's proposed multi-factor test.

amici curiae in *Bruesewitz*—as they have already done at the petition stage, see National Vaccine Information Center et al. Amici Br. 2, *Bruesewitz*, *supra*. Likewise, manufacturers of vaccines at issue in the OAP would be able to present their views in *Bruesewitz*.

Accordingly, the Court should grant the petition in *Bruesewitz*. The Court could hold the petition in this case pending *Bruesewitz*, or else simply deny the petition to avoid the idiosyncratic mootness question, cf. *ASARCO Inc.* v. *Kadish*, 490 U.S. 605, 621 n.1 (1989).

CONCLUSION

The petition for a writ of certiorari should be held pending the disposition of *Bruesewitz* v. *Wyeth, Inc.*, petition for cert. pending, No. 09-152, or be denied. The petition for a writ of certiorari in *Bruesewitz* should be granted.

Respectfully submitted.

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AMERICAN HOME PRODUCTS CORP. D/B/A WYETH, *et al.*,
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v.

MARCELO A. FERRARI AND CAROLYN H. FERRARI, Individually and as Parents and Next Friend of STEFAN R. FERRARI,
Respondents.

On Petition for a Writ of Certiorari to the Supreme Court of Georgia

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STATEMENT OF INTEREST OF AMICI CURIAE

Founded in 1930, amicus curiae the American Academy of Pediatrics ("AAP") is a national, not-for-profit organization dedicated to furthering the interests of children's health.[1] Since AAP's inception, its

[1] Pursuant to Sup. Ct. R. 37.2(a), amici curiae note that counsel of record for all parties received notice at least 10 days prior to the due date of AAP's intention to file this brief. Pursuant to Sup. Ct. R. 37.6, amici note that no part of this brief was authored by counsel for any party. Amici also note

membership has grown from 60 pediatricians to over 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 79 years, AAP has become a powerful voice for children's health through education, research, advocacy, and the provision of expert advice. AAP has worked with the federal and state governments, health care providers, and parents on behalf of America's children to ensure the availability of safe and effective childhood vaccines, the vast majority of which are administered in pediatricians' offices after careful consultation with parents.

Amicus curiae the AAP Section on Infectious Diseases was founded in 1990. It is comprised of AAP members who have a special interest in pediatric infectious diseases.

Amicus curiae the American Academy of Family Physicians ("AAFP") is a medical specialty society founded in 1947 to promote the science and art of family medicine. It is one of the largest medical organizations in the United States, with more than 94,000 members. The AAFP endorses the concept that all children and adults should have access to all immunizations recommended by the organization.

Amicus curiae the American College of Osteopa Pediatricians ("ACOP") is the official pediatric organization of the American Osteopathic Association. ACOP's advocacy efforts represent the interests of all U.S. osteopathic pediatricians before Congress and

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that no party or counsel made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or entity other than amici or their members made such a monetary contribution. This brief is filed with the consent of all parties.

other governmental bodies as well as in coalition with other organizations that focus on children's welfare.

Amicus curiae the American Medical Association ("AMA"), an Illinois non-profit corporation, is a national association of approximately 240,000 physicians, residents, and medical students. The AMA is the largest medical society in the United States. Its members practice in every state and in every field of medical specialization, including pediatrics. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. The AMA has long been a vocal advocate of the importance of vaccines in maintaining high standards of public health in the United States.

Founded in 1872, amicus curiae the American Public Health Association ("APHA"), is the oldest and most diverse organization of public health professionals in the world. The association aims to protect all Americans and their communities from preventable, serious health threats and strives to assure that population-based health promotion and disease prevention activities and preventive health services are universally accessible in the United States. APHA represents a broad array of health providers, educators, environmentalists, policymakers, and health officers. APHA has a long-standing policy in support of safe and effective vaccines for children.

Amicus curiae Every Child By Two ("ECBT") is a non-profit health advocacy organization based in the United States and dedicated to protecting children from disease through promotion of vaccinations and raising parental awareness of potential vaccine

benefits. ECBT was founded in 1991 by former First Lady of the United States Rosalynn Carter and former First Lady of Arkansas Betty Bumpers.

Amicus curiae the Immunization Action Coalition ("IAC") is a non-profit organization that works to increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public that enhance the delivery of safe and effective immunization services. IAC also facilitates communication about the safety, efficacy, and use of vaccines within the broad immunization community of patients, parents, healthcare organizations, and government health agencies.

Amicus curiae the Infectious Diseases Society of America ("IDSA") represents more than 8,500 infectious disease physicians and scientists devoted to patient care, research, prevention, and public health. IDSA's purpose is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases. Its members care for patients of all ages with serious and life-threatening infections, including vaccine-preventable diseases.

Amicus curiae the Pediatric Infectious Diseases Society ("PIDS") is the world's largest organization of professionals dedicated to the treatment, control, and eradication of infectious diseases affecting children. PIDS's mission is to enhance the health of infants, children, and adolescents by promoting excellence in diagnosis, management, and understanding of infectious diseases through clinical care, education, research, and advocacy.

Amicus curiae the Vaccine Education Center at the Children's Hospital of Philadelphia was launched in 2000 to provide accurate, comprehensive, and up-to-date information about vaccines and the diseases they prevent to parents and healthcare professionals. The Center communicates facts about vaccines, including how vaccines are made, how and why vaccines work, who recommends them, whether they are safe, whether they are still necessary, and when they should be administered to patients.

Amici—all of whom support the routine vaccination of children against a host of vaccine-preventable infectious diseases—urge this Court to grant the petition and reverse the judgment of the Supreme Court of Georgia below. As explained below, Congress enacted the National Childhood Vaccine Injury Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-1 *et seq.* to avert a public health crisis and thus safeguard the Nation's vaccine supply. As the Third Circuit recently recognized, Congress achieved that objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz* v. *Wyeth Inc.*, __ F.3d __, 2009 WL 792468, at *13 (3d Cir. Mar. 27, 2009) (emphasis added).

The Supreme Court of Georgia below reached the exact opposite conclusion, holding that design defect claims are preempted only "if it is determined, *on a case-by-case basis*, that the particular vaccine was unavoidably unsafe." Pet. App. 15-16 (emphasis added). That decision—which allows judges *and juries* to decide whether a particular vaccine can be made safer—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene

through the passage of the Vaccine Act" in the first place. *Bruesewitz*, 2009 WL 792468, at *13. The petition thus presents an issue of exceptional importance that warrants this Court's review.

SUMMARY OF ARGUMENT

The public health benefits of childhood vaccines cannot be overstated. Because of vaccines, a number of debilitating and life-threatening infectious diseases have been eliminated or virtually eliminated in this country, providing not only significant savings in direct and indirect costs, but also enhancing the length and quality of life of countless children. It is no wonder that Congress has declared that "[t]he availability and use of vaccines to prevent childhood diseases is among the Nation's top public health priorities." H.R. Rep. No. 99-908, at 5 (1986).

In the mid-1980s, the number of vaccine-related lawsuits filed against vaccine manufacturers rose sharply. Although the tort system failed to provide adequate compensation for many children injured by vaccines, the flood of vaccine-related litigation overwhelmed vaccine manufacturers. A genuine threat to the public health emerged as manufacturers abandoned or considered abandoning the vaccine market. As the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *National Childhood Vaccine Injury Compensation Act of 1985: Hearing Before the S. Comm. on Labor and Human Resources*, 99th Cong. 8 (Dec. 9, 1985) (hereinafter "*Dec. 9, 1985 Hearing*") (statement of Martin Smith, M.D., President of the AAP).

Congress responded by passing the Vaccine Act. The Act established a no-fault alternative compensation program intended to provide adequate compensation to children injured by vaccines and to ensure the stability of the vaccine market and thus safeguard the Nation's vaccine supply. As the Third Circuit recently recognized, the Act furthers that latter objective in part by expressly preempting "*all* design defect claims, including those based in negligence." *Bruesewitz*, 2009 WL 792468, at *13 (emphasis added).

In the decision below, the Supreme Court of Georgia reached a contrary conclusion, holding that design defect claims are preempted only "if it is determined, *on a case-by-case basis*, that the particular vaccine was unavoidably unsafe." Pet. App. 15-16 (emphasis added). As the Third Circuit explained in expressly rejecting that conclusion, if the Vaccine Act is interpreted "to allow case-by-case analysis of whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Bruesewitz*, 2009 WL 792468, at *29 (emphasis added). Thus, if allowed to stand, the decision below could precipitate the same crisis that Congress sought to avert in passing the Vaccine Act: "the very real possibility of vaccine shortages, and, in turn an increasing number of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

REASONS FOR GRANTING THE WRIT

I. VACCINE DEVELOPMENT IS ONE OF THE GREATEST PUBLIC HEALTH ACHIEVEMENTS OF THE TWENTIETH CENTURY.

The "[v]accination of children against deadly, disabling, but preventable infectious disease has been one of the most spectacularly effective public health initiatives this country has ever undertaken." *Id.* at 4. *See also* Centers for Disease Control and Prevention, *Ten Greatest Public Health Achievements—United States, 1900-1999*, 48 MMWR 241 (Apr. 2, 1999) (listing vaccination as one of the ten greatest public health achievements of the twentieth century). Indeed, "the sharp and deep reduction in [infectious] diseases * * * is [largely] attributable to the development and employment of effective vaccines." *Immunization and Preventive Medicine, 1982: Hearing Before the Subcomm. on Investigations and General Oversight of the S. Comm. on Labor and Human Resources*, 97th Cong. 103 (May 7, 1982) (hereinafter "*1982 Hearing*") (statement of Vincent A. Fulginiti, Chairman, Committee on Infectious Diseases, AAP).

Because of vaccines, smallpox has been eradicated worldwide, Sandra W. Roush, *et al.*, *Historical Comparisons of Morbidity and Mortality for Vaccine-Preventable Diseases in the United States*, 298 JAMA 2155, 2160 (2007), and polio, diphtheria, and tetanus have essentially been eliminated in the United States. H.R. Rep. No. 99-908, at 5. In 2007, cases of measles, mumps, rubella, and pertussis (whooping cough) were reduced by more than 90% of twentieth century baseline levels. American Academy of

Pediatrics, *Red Book: 2009 Report of the Committee on Infectious Diseases* 2 (forthcoming 28th ed. 2009).

The significance of these developments is beyond dispute: "[C]hildren in the United States enjoy substantial freedom from the ravages of once common communicable infectious diseases and illnesses. These illnesses limited life expectancy and left tens of thousands disabled in their wake." *1982 Hearing*, *supra*, at 103 (statement of Vincent A. Fulginiti, Chairman, Committee on Infectious Diseases, AAP). Vaccines have enhanced not only the length and quality of life of countless children who have been vaccinated but also that of others in the community who are unable to be vaccinated but whose risk of exposure to an infectious disease has been reduced accordingly. Institute of Medicine, *Financing Vaccines in the 21st Century: Assuring Access and Availability* 27 (2004). It has been estimated that vaccination with just seven of the routinely recommended childhood vaccines "prevents an estimated 33,000 deaths and 14 million cases of disease in every birth cohort." Roush, *et al.*, *supra*, at 2160.

Vaccines have also translated into direct savings in medical costs, as well as increased productivity from families that would otherwise be burdened by disease. Institute of Medicine, *supra*, at 27-29. It has been estimated that for every dollar invested in childhood vaccination against nine vaccine-preventable diseases, $5.80 is saved in direct medical costs; $17.70 is saved when indirect benefits, such as lost productivity, are taken into account. Walter A. Orenstein, *et al.*, *Immunizations in the United States: Success, Structure, and Stress*, 24 Health Affairs 599, 600 (2005). Overall, "[b]illions of medi-

cal and health-related dollars have been saved by immunizations." H.R. Rep. No. 99-908, at 4.

Of course, "[n]o vaccine is completely safe or effective." Centers for Disease Control and Prevention, *General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 55 MMWR 1 (Dec. 1, 2006). *See* H.R. Rep. No. 99-908, at 6 ("There is today no 'perfect' or reaction-free childhood vaccine on the market."). Even when vaccines are properly manufactured, distributed, and administered, a small number of children may suffer rare but serious adverse reactions. *See* H.R. Rep. No. 99-908, at 4, 6. "Despite these possibilities, public health officials, private physician groups, and parent organizations have repeatedly stated that it is safer to take the required shots than to risk the health consequences of contracting the diseases immunizations are designed to prevent." *Id.* at 6. In other words, the enormous benefits of vaccination vastly outweigh the small risk of injury. *See General Recommendations on Immunization*, *supra*, at 1 ("[R]ecommendations for vaccination practices balance scientific evidence of benefits for each person and to society against the potential costs and risks for vaccination for the individual and programs."); H.R. Rep. No. 99-908, at 6 ("in light of the overall success of immunization programs, the Federal government continues to support * * * immunizations to children").

II. CONGRESS ENACTED THE VACCINE ACT TO PROVIDE ADEQUATE COMPENSATION TO CHILDREN INJURED BY VACCINES AND TO SAFEGUARD THE NATION'S VACCINE SUPPLY.

In 1986, the Nation faced a public health crisis. Vaccine-related lawsuits against vaccine manufacturers had spiked, and rising litigation and insurance costs threatened to halt vaccine production in the United States. H.R. Rep. No. 99-908, at 4, 6-7. At the same time, however, the tort system had failed to provide adequate compensation for children injured by vaccines. *Id.* at 6. Congress responded by enacting the Vaccine Act, thereby ensuring adequate compensation for children injured by vaccines and safeguarding the Nation's vaccine supply.

A. The Costs Of Vaccine-Related Litigation Had Threatened To Halt Vaccine Production In The United States.

In the mid-1980s, the number of vaccine-related suits filed against vaccine manufacturers increased markedly. *Id.* at 4. According to a 1985 survey of the seven manufacturers producing childhood vaccines,[2] between January 1980 and March 1985, 299 lawsuits were filed against them seeking compensation for vaccine-related injuries; 84 percent of those suits were related to childhood vaccines. Staff of H. Subcomm. on Health and the Environment of the Comm. on Energy and Commerce, 99th Cong., *Childhood Immunizations* 86 (Comm. Print 1986) (hereinafter

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[2] Two of the manufacturers were operated by State organizations in Michigan and Massachusetts. H.R. Rep. No. 99-908, at 7.

"*Childhood Immunizations*"). About 60 percent of all the suits filed sought damages in the aggregate of $3.5 billion. *Id.* Between 1983 and 1984 alone, litigation costs nearly doubled—jumping from $4.7 million to $9.8 million. *Id.* at 87.

With the deluge of lawsuits, vaccine manufacturers faced rising insurance premiums and a decreasing pool of insurers willing to cover them. H.R. Rep. No. 99-908, at 6-7; *Childhood Immunizations*, *supra*, at 73; *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 99th Cong. 288 (July 18, 1985) (hereinafter "*July 18, 1985 Hearing*") (statement of Stephen White, Vice President of Reed-Stenhouse, Ltd.) (explaining that insurance companies were struggling with losses from pharmaceutical, asbestos, and pollution claims). As litigation and insurance costs soared, "the prices of vaccines * * * jumped enormously," H.R. Rep. No. 99-908, at 4—in some cases as much as 900 percent, *see Childhood Immunizations*, *supra*, at 90—and "[t]he number of childhood vaccine manufacturers * * * declined significantly." H. Rep. No. 99-908, at 4.

As it became increasingly clear that vaccine prices could not forever keep pace with escalating litigation and insurance costs, *see, e.g.*, *July 18, 1985 Hearing*, *supra*, at 240 (statement of Robert Johnson, President of Lederle Laboratories) (noting that "vaccine pricing" of the previous year would not "cover the projected costs of liability" for the following year), the few remaining vaccine manufacturers began "to question their continued participation in the vaccine market." H.R. Rep. No. 99-908, at 7. *See July 18, 1985 Hearing*, *supra*, at 256 (statement of Robert

Johnson, President of Lederle Laboratories) ("If the current trend of spiraling litigation continues or worsens, there * * * is a very real possibility that we will be forced to abandon the vaccine business."); *id.* at 284 (statement of David J. Williams, Vice President and General Manager of Connaught Laboratories, Inc.) ("There is always a possibility that Connaught will be unable to remain in the vaccine business.").

As Congress recognized, "[t]he loss of any of the existing manufacturers of childhood vaccines * * * could create a genuine public health hazard in this country." H.R. Rep. No. 99-908, at 7. At that time, "there [was] only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the [diphtheria, pertussis, and tetanus] DPT vaccine." *Id.*[3] Thus, as the then-President of the AAP testified: "The threat to our vaccine supply in this country is a real one * * *. We could lose the remainder of our suppliers unless some positive legislative action is taken." *Dec. 9, 1985 Hearing*, *supra*, at 8 (statement of Martin Smith, M.D., President of the AAP).

B. The Tort System Had Failed To Provide Adequate Compensation For Children Injured By Vaccines.

Ironically, while lawsuits against vaccine manufacturers skyrocketed, some children injured by vaccines failed to receive any compensation. Despite their injuries, some children were simply not deemed

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[3] Michigan and Massachusetts also produced their own DPT vaccine. H.R. Rep. No. 99-908, at 7.

good "candidates for litigation," *National Childhood Vaccine-Injury Compensation Act: Hearing Before the S. Committee on Labor and Human Resources*, 98th Cong. 171 (May 3, 1984) (hereinafter "*1984 Hearing*") (statement of Andrew Dodd, Attorney at Ward, Dodd & Grant, Torrance, California), because any prospective recovery was not "large enough" to make their cases attractive to an attorney. *Id.* at 146 (statement of Martin H. Smith, M.D., President-elect of the AAP).

Thus, while a few lawsuits reaped multi-million dollar awards, some injured children received no compensation at all. 132 Cong. Rec. H9943, H9952 (Oct. 14, 1986) (statement of Rep. Waxman); *id.* at H9954 (statement of Rep. Biaggi); *1984 Hearing*, *supra*, at 4 (statement of Senator Kennedy) (tort system "awards few handsomely and sends others equally aggrieved away penniless"). The tort system was thus aptly described as a "lottery." *1984 Hearing*, *supra*, at 277 (statement of John E. Lyons, President of Merck Sharp & Dohme).

C. The Vaccine Act Provides Adequate Compensation To Children Injured By Vaccines And Ensures The Stability Of The Vaccine Market And The Nation's Vaccine Supply.

Congress responded to the looming crisis by enacting the Vaccine Act. The overriding goals of the Act were two-fold: (1) to ensure adequate compensation for children injured by vaccines, and (2) to stabilize the vaccine market and safeguard the Nation's vaccine supply. H.R. Rep. No. 99-908, at 7.

Congress addressed both of those goals in part by establishing the National Vaccine Injury Compensation Program ("VICP"), a no-fault alternative compensation system under which children injured by certain vaccines would receive "fair and expeditious" compensation for their injuries. *Id.* at 12. *See* 42 U.S.C. § 300aa-10 *et seq.* Under the VICP, a person seeking compensation for an injury caused by a vaccine covered by the Act must file a petition with the United States Court of Federal Claims, which refers the petition to a "Vaccine Court"—an office within the court of special masters appointed to four-year terms by the court to hear VICP claims. 42 U.S.C. §§ 300aa-11(a)(1)-(2), 300aa-12(c), 300aa-21(a). The Secretary of Health and Human Services is named as a respondent; vaccine manufacturers are not parties to VICP proceedings. *Id.* § 300aa-12(b)(1).

A petitioner is entitled to compensation if he or she has suffered an injury set forth in the "Vaccine Injury Table"—a table of vaccines and the injuries presumed to be caused by those vaccines—unless it can be shown by a preponderance of the evidence that the petitioner's injury was not caused by the vaccine. *Id.* §§ 300aa-11(b), (c), 300aa-13(a)(1), 300aa-14. A petitioner who has not suffered a "Table Injury" may still obtain compensation by proving that his or her injury was in fact caused by a vaccine covered by the Act. *Id.* § 300aa-11(c)(1)(C)(ii). *See Grant* v. *Secretary of HHS*, 956 F.2d 1144, 1147-48 (Fed. Cir. 1992).[4] Payment of compensation is made

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[4] The special masters of the Vaccine Court have developed a proficiency in the complex medical and scientific issues involved in causation claims. Indeed, the Court of Federal Claims

from a "Vaccine Injury Compensation Trust Fund"—funded by a manufacturers excise tax on those vaccines covered by the Act, *see* 26 U.S.C. §§ 4131, 9510—on a no-fault basis. 42 U.S.C. §§ 300aa-13,

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recently observed that "instead of being passive recipients of information, such as jurors, special masters are given an active role in determining the facts relevant to Vaccine Act petitions," and that "special masters have the expertise and experience to know the type of information that is most probative of a claim." *Doe* v. *Secretary, HHS*, 76 Fed. Cl. 328, 338-339 (2007).

The expertise of the special masters in evaluating causation claims was recently demonstrated in an Omnibus Autism Proceeding established under the VICP to determine whether there is a causal link between childhood vaccines and autism. Approximately 5,000 cases alleging an association between autism and either the MMR vaccine (which does not contain thimerosal) or vaccines containing the preservative thimerosal, or both, have been filed with the Vaccine Court. *See* http://www.hrsa.gov/vaccinecompensation. On February 12, 2009, three special masters issued voluminous opinions evaluating evidence based on the theory that the MMR vaccine, in combination with vaccines containing the preservative thimerosal, causes autism. *See Cedillo* v. *Secretary of HHS*, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009); *Hazlehurst* v. *Secretary of HHS*, 2009 WL 332306 (Fed. Cl. Feb. 12, 2009); *Snyder* v. *Secretary of HHS*, 2009 WL 332044 (Fed. Cl. Feb. 12, 2009). All three cases rejected the proposition that the vaccines in question caused autism.

In reaching those conclusions, the special masters in each case considered a wealth of scientific evidence. As the special master in *Snyder* observed: "The evidentiary record in this case * * * encompasses, *inter alia*, nearly four weeks of testimony, including that offered in the *Cedillo* and *Hazlehurst* cases; over 900 medical and scientific journal articles; 50 expert reports (including several reports of witnesses who did not testify); supplemental expert reports filed by both parties post-hearing, [and] the testimony of fact witnesses on behalf of [the injured child and his] medical records." *Snyder*, 2009 WL 332044, at *8.

300aa-14, 300aa-15(i). Since 1989, the Vaccine Court has issued more than 2,200 awards totaling over $1.7 billion. *See* National Vaccine Injury Compensation Program, *Statistic Report* (Apr. 3, 2009), *available at* http://www.hrsa.gov/vaccinecompensation/statistics_report.htm.

After the Vaccine Court has issued a final judgment, a petitioner may accept or reject it. 42 U.S.C. § 300aa-21(a).[5] Although a party who rejects the Vaccine Court's judgment may pursue certain *limited* claims in state or federal court, design defect claims are not among them. *Id.* § 300aa-21(a), (b). As the Third Circuit recently recognized, Congress expressly preempted "*all* design defect claims, including those based in negligence." *Bruesewitz*, 2009 WL 792468, at *13 (emphasis added). *See* 42 U.S.C. § 300aa-22(b)(1). If an injured person has such a claim, he or she "should pursue recompense in the compensation system, not the tort system." H.R. Rep. No. 99-908, at 26. The preemption of all design defect claims is critical to Congress's objective of stabilizing the vaccine market and safeguarding the Nation's vaccine supply. As the Third Circuit explained: "Congress[] belie[ved] that an alternate compensation system would reduce awards and create a stable, predictable basis for estimating liability." *Bruesewitz*, 2009 WL 792468, at *12. Indeed, as the legislative history makes clear, Con-

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[5] The Vaccine Act also authorizes petitioners to "opt out" of a VICP proceeding if a special master has not resolved his or her petition within 240 days or if the Court of Federal Claims has not completed its review of a special master's decision within 420 days of the date on which the petition was filed. *See* 42 U.S.C. § 300aa22(b).

gress "believe[d] that once this system [was] in place and manufacturers ha[d] a better sense of their potential litigation obligations, a more stable childhood vaccine market [would] evolve." H.R. Rep. No. 99-908, at 7.

III. THE DECISION BELOW—WHICH DIRECTLY CONFLICTS WITH A DECISION OF A FEDERAL COURT OF APPEALS—POSES A THREAT TO THE FUTURE PRODUCTION AND DEVELOPMENT OF VACCINES.

Contrary to all clear indications of congressional intent, the Supreme Court of Georgia held below that design defect claims are preempted only "if it is determined, *on a case-by-case basis*, that the particular vaccine was unavoidably unsafe." Pet. App. 15-16 (emphasis added). As the Third Circuit recently concluded, that interpretation of the Vaccine Act is simply wrong. *See Bruesewitz*, 2009 WL 792468, at *11. As the Third Circuit explained, if the Act is interpreted "to allow case-by-case analysis of whether particular vaccine side effects are avoidable," then "*every* design defect claim is subject to evaluation by a court." *Id.* at *12 (emphasis added).

If that were the case, "[e]ach of the objectives extolled [in the Vaccine Act's legislative history] would be undermined." *Id.* at 36. Thus, the decision below—which allows judges *and juries* to decide whether a particular vaccine can be made safer—threatens a resurgence of "the very problems which led to instability in the vaccine market and which caused Congress to intervene through the passage of the Vaccine Act" in the first place. *Id.* That threat is extremely palpable, as the recent decisions issued by the Vaccine Court promise to unleash a barrage of

claims in the courts. *See supra* at 16 n.4. If allowed to stand, therefore, the decision below could drive vaccine manufacturers from the market and halt the future production and development of childhood vaccines in this country.

A. Unpredictable Litigation Costs Could Once Again Force Vaccine Manufacturers To Abandon Or Consider Abandoning The Vaccine Market.

By eliminating the threat of most lawsuits, the Vaccine Act has prevented manufacturers from abandoning the vaccine market, thus ensuring a stable supply of vaccines. *See* Louis Z. Cooper, *et al.*, *Protecting Public Trust in Immunization*, 122 Pediatrics 1, 2 (2008). By allowing case-by-case consideration of whether vaccines are unavoidably unsafe, the decision below will "undoubtedly increase the costs and risks associated with litigation and [will] undermine a manufacturer's efforts to estimate and control costs." *Bruesewitz*, 2009 WL 792468, at *13. Thus, the decision creates the "very real possibility" that vaccine manufacturers will once again abandon or be forced to consider abandoning the vaccine market. H.R. Rep. No. 99-908, at 7.

That is particularly so given the precarious state of the vaccine industry. Today, as in 1986, there continues to be only *one* manufacturer of the MMR vaccine, and only *two* manufacturers of the DTP vaccine. American Academy of Pediatrics, *Status of Licensure and Recommendations for New Vaccines*, Red Book Online (2009), *available at* http://aapredbook.aappublictions.org/news/vaccstatus.shtml; *Childhood Immunizations*, *supra*, at 67; H.R. Rep. No. 99-908, at 7. And while the Vaccine

Act has been instrumental in preventing manufacturers from fleeing the vaccine market, the number of vaccine manufacturers has not greatly increased since the Act's passage. *See Status of Licensure and Recommendations for New Vaccines, supra.* The costs of developing and producing vaccines have also increased over the years. Between 1991 and 2003, costs for research and development, postlicensure clinical studies, and production process improvements grew from $231 million to $802 million. Stanley A. Plotkin, *et al.*, *Vaccines* 38 (2008).

Thus, vaccine manufacturers today are no better—and, indeed, are perhaps even more poorly—situated to handle the unpredictability and expense of litigation. Yet, as was true in 1986, "the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn an increasing number of unimmunized children, and, perhaps, a resurgence of preventable diseases." H.R. Rep. No. 99-908, at 7.

B. The Progress That Has Been Made In Vaccine Development Since The Passage Of The Vaccine Act Could Come To A Halt.

In addition to ensuring the stability of the existing childhood vaccine market, one of Congress's objectives in passing the Vaccine Act was ensure "that a greater number of vaccine products will become available to prevent disease." H.R. Rep. No. 99-908, at 4. In that regard, the Act has been unquestionably successful. Vaccine development has flourished since 1986 with the number of vaccine-preventable diseases having more than doubled. *See Childhood Immunizations, supra*, at 1; Centers for Disease

Control and Prevention, *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years–United States*, 57 MMWR Q1-Q4 (Jan. 2, 2009).

In 1986, children were routinely vaccinated against seven diseases (diphtheria, measles, mumps, pertussis, poliomyelitis, rubella, and tetanus). *Childhood Immunizations*, *supra*, at 1. Today, children are also routinely immunized against an additional eight diseases: *haemophilus influenzae* type b (Hib), hepatitis A, hepatitis B, influenza, meningococcal disease, pneumococcal disease, rotavirus, and varicella (chicken pox). *Recommended Immunization Schedules for Persons Aged 0 Through 18 Years United States*, *supra*, at Q1-Q4. Research and development of new vaccines is always ongoing. *See* Immunization Action Coalition, *Vaccine-Related Journal Articles, available at* http://www.immunize.org/journal artcles/toipoten.asp (listing, by year, published articles regarding vaccine development).

Vaccine manufacturers face many challenges in bringing new vaccines to market. *See* Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 Health Affairs 624, 623-629 (2005). In addition to research and development, vaccine manufacturers are also "almost exclusively" responsible for the production and distribution of such vaccines. *See* Orenstein, *et al.*, *supra*, at 601-603. As noted, by eliminating the threat of most lawsuits, the Vaccine Act has kept manufacturers from abandoning vaccine production. *See* Cooper, *et al.*, *supra*, at 2. If the decision below is allowed to stand, the prognosis for future vaccine development is extremely poor.

CONCLUSION

For the foregoing reasons, and those stated in the petition, the petition for a writ of certiorari should be granted, and the judgment below reversed.

Respectfully submitted,

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In the
Supreme Court of the United States

AMERICAN HOME PRODUCTS CORP. d/b/a/ WYETH, *et al.*,

Petitioners,

v.

MARCELO A. FERRARI, *et al.*,

Respondents.

On Petition for Writ of Certiorari to the Supreme Court of Georgia

BRIEF AMICUS CURIAE OF PACIFIC LEGAL FOUNDATION IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

In the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers out of the market, causing shortages of vaccines essential to public health programs. Congress averted a public health crisis by enacting the National Childhood Vaccine Injury Act of 1986. The Act shielded vaccine manufacturers from categories of tort litigation, directed federal agencies to develop safer childhood vaccines, and established a Vaccine Court to administer a no-fault remedy for vaccine-related injuries. The Act's express preemption provision states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." 42 U.S.C. § 300aa-22(b)(1).

Does the Vaccine Act expressly preempt a state-law claim against a vaccine manufacturer based on an allegation that the vaccine-related injury could have been avoided by a vaccine design allegedly safer than the one approved by the United States Food and Drug Administration for use nationwide?

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IDENTITY AND INTEREST OF AMICUS CURIAE

Pacific Legal Foundation (PLF) respectfully submits this brief amicus curiae in support of the Petitioners.[1]

PLF was founded more than 35 years ago and is widely recognized as the largest and most experienced nonprofit legal foundation of its kind. PLF litigates matters affecting the public interest at all levels of state and federal courts and represents the views of thousands of supporters nationwide. In furtherance of PLF's continuing mission to defend individual and economic liberties, the Foundation created its Free Enterprise Project. Through that project, the Foundation seeks to protect the free enterprise system from abusive regulation, the unwarranted expansion of claims and remedies in state civil justice systems, and barriers to the freedom of contract. To that end, PLF participated as Amicus Curiae in this case in the Georgia Supreme Court. *Am. Home Prod. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008). PLF also participated in several cases before this Court and others on matters affecting the public interest, including issues of preemption and the impact of

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[1] Pursuant to this Court's Rule 37.2(a), all parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the Amicus Curiae's intention to file this brief. Letters evidencing such consent have been filed with the Clerk of the Court.

Pursuant to Rule 37.6, Amicus Curiae affirms that no counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than Amicus Curiae, its members, or its counsel made a monetary contribution to its preparation or submission.

burdensome state regulations on America's economic vitality. *See, e.g., Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644 (2003), *Preston v. Ferrer*, 128 S. Ct. 978 (2008), and *Bank of Am. v. City and County of San Francisco*, 309 F.3d 551 (9th Cir. 2002). PLF attorneys also have published on the public policies supporting tort reform. *See, e.g.*, Deborah J. La Fetra, *Freedom, Responsibility, and Risk: Fundamental Principles Supporting Tort Reform*, 36 Ind. L. Rev. 645 (2003). PLF believes its public policy experience will assist this Court in its consideration of the petition.

REASONS FOR GRANTING THE WRIT

I

RESTORING THE INTEGRITY OF THE VACCINE ACT IS A MATTER OF EXCEPTIONAL, NATIONWIDE IMPORTANCE

The Vaccine Act was enacted in response to a public health emergency of severe vaccine shortages in the mid-1980s due to pharmaceutical companies reacting to threats of extraordinary litigation costs from alleged vaccine-related injuries by withdrawing from the market, leaving children vulnerable to disease. To revitalize the shrinking vaccine market while efficiently compensating the victims of vaccines' rare but inevitable side effects, Congress designed a national statutory scheme to prevent co-regulation of the vaccine market via state tort law. As an alternative to the traditional state tort system, the Vaccine Act provides a federal no-fault compensation program in which people injured by vaccines obtain quick and decisive compensation in exchange for manufacturers' immunity from state tort claims.

If plaintiffs reject the Vaccine Court's decision, the statute expressly restricts the types of state-law claims that the plaintiffs can pursue in state court, primarily by declaring that all federally approved vaccines are unavoidably unsafe, and leaving to the Food and Drug Administration the task of determining which vaccines were nonetheless safe enough to go on the market. 42 U.S.C. § 300aa-22(b)(1). Consistent with the purpose of the Act to reduce the threat of litigation against vaccine manufacturers, Congress used this language apparently to preclude ad hoc jury determinations on the question of safe design. However, by employing a strained reading of legislative history and ignoring the fundamental impetus to reduce lawsuits that drove enactment of the Vaccine Act in the first place, the Georgia Supreme Court subverts the fundamental purpose of the Vaccine Act, putting the nation at risk for reduced availability of vaccines and consequent exposure to preventable diseases. This decision stands in direct conflict with the Third Circuit's decision in *Bruesewitz v. Wyeth Inc.*, 2009 WL 792468, *12, *19 (3d. Cir. 2009) (finding the "Ferrari Court's construction is contrary to the structure of the Act" and holding that "design defect claims are expressly preempted by the Vaccine Act.").

A. The Vaccine Act Was Enacted in an Era of Litigation Crisis

Vaccines are undisputedly an important public health measure that create tremendous benefits to American citizens. However, these benefits were threatened by a litigation crisis that could have crippled the vaccine industry. In response, Congress enacted the Vaccine Act to protect the nation's vaccine

supply and to ensure quick and decisive compensation for vaccine-related injuries.

Vaccines are considered by doctors and public health experts as the "'single most effective [means of] health prevention,'" due to their overwhelming success in reducing the incidence of communicable diseases. Elizabeth A. Breen, *A One Shot Deal: The National Childhood Vaccine Injury Act*, 41 Wm. & Mary L. Rev. 309, 311-12 (1999) (citation omitted). At the turn of the twentieth century, infectious disease proved to be among the greatest health risks threatening the American population. *Id.* (citing H.R. Rep. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6345) ("Vaccination of children against deadly, disabling, but preventable infectious diseases has been one of the most spectacularly effective public health initiatives this country has ever undertaken."). In the "fundamentally prevaccine era," for the week ending June 8, 1946, health departments reported 161 cases of polio, 229 cases of diphtheria, 1,886 cases of pertussis, and 25,041 cases of measles. United States Center for Disease Control and Prevention, *Historical Perspectives Notifiable Disease Surveillance and Notifiable Disease Statistics–United States, June 1946 and June 1996*, 45 Morbidity & Mortality Wkly. Rep. 530-36 (June 28, 1996) (*Historical Perspectives*).[2] In stark contrast, after vaccines were made readily available to the public, the Center for Disease Control reported "a cumulative total of no confirmed cases of polio, one case of diphtheria, 1419 cases of pertussis,

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[2] *Available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00042744.htm (last visited Mar. 16, 2009).

and 263 cases of measles have been reported for 1996." *Id.*

Recognizing the compelling public health benefits achieved by widespread vaccination, the Supreme Court, in a decision as early as 1905, upheld a local ordinance mandating that each individual receive the smallpox vaccine. *Jacobson v. Massachusetts*, 197 U.S. 11, 35 (1905) ("Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was—perhaps, or possibly--not the best either for children or adults."). Emboldened by this ruling, states immediately followed suit to enact mandatory vaccination statutes, and every state today requires children to be immunized before attending public school, and many have immunization laws for private schools as well. Derry Ridgway, *No-Fault Vaccine Insurance: Lessons From the National Vaccine Injury Compensation Program*, 24 J. Health Pol. Pol'y & L. 59, 60 (1999).

The successes of mandatory widespread vaccinations were immediate and apparent. For example, while there were a total of 337 reported cases of smallpox in 1946, the last documented cases of smallpox in the United States occurred just three years later in 1949. United States Center for Disease Control and Prevention, *Historical Perspectives*, 45 Morbidity & Mortality Wkly. Rep. 530-36. In 1980, the World Health Organization declared that smallpox had been totally eradicated; today the virus is no longer found outside of laboratories and the vaccination is no longer given routinely in the United

States. *Id.* Widespread polio vaccinations were similarly successful. Between 1955 and 1962, physicians and public health agencies administered 400 million doses of the polio vaccine across the United States. Paul A. Offit, *Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?*, 24 Health Affairs 622 (May 25, 2005).[3] As a result, the number of children paralyzed by polio decreased from 15,000 each year to zero. Paul A. Offit, *Lawsuits Won't Stop Pandemics*, Wall St. J., Dec. 1, 2005, at A16.[4]

Vaccines have been the single most powerful force in enhancing the length and quality of life for the vast majority of Americans. "[D]uring the 20th century, the lifespan of Americans increased by 30 years—mostly because of vaccines." *Id.* Vaccines provide an "extremely cost-effective technology for dealing with killer diseases, saving lives, and averting millions of dollars of potential health spending" in the United States. Patricia M. Danzon, *et al.*, *Vaccine Supply: A Cross-National Perspective*, 24 Health Affairs 706 (May 27, 2005).[5] Vaccines have saved countless lives and greatly improved the health of millions.

Although vaccines are evidently beneficial to a vast number of recipients, they may pose harmful side effects to a small number of children, as is true for any pharmaceutical product. Paula Jacobi, *Pharmaceutical*

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[3] *Available at* http://www.medscape.com/viewarticle/504779 (last visited Mar. 16, 2009).

[4] *Available at* http://www.phrma.org/news_room/press_releases/lawsuits_won%27t_stop_pandemics/ (last visited Mar. 16, 2009).

[5] *Available at* http://www.medscape.com/viewarticle/504780 (last visited Mar. 16, 2009).

Tort Liability: A Justifiable Nemesis to Drug Innovation and Access?, 38 J. Marshall L. Rev. 987, 989 (2005). But of all the medical procedures or pharmaceuticals that carry risks to the recipient, vaccines are especially prone to blame for potential adverse side effects because they are widely administered to young children who appear perfectly healthy at the time of their vaccinations. Inevitably, with a steady flow of millions of vaccinations given each year in the United States, cases of alleged vaccine-related injuries began to surface both in the media and in the courts.

One vaccine in particular, the Diphtheria-Pertussis-Tetanus (DPT) vaccine developed in the 1920s, generated sharp public criticism due to highly publicized cases of the alleged injuries that it caused to children. During the 1970s, increasing numbers of injured persons filed "ever larger claims against manufacturers" of vaccines. Ridgway, *No-Fault Vaccine Insurance*, 24 J. Health Pol. Pol'y & L. at 60. A television documentary in 1982, "DPT Vaccine Roulette," featured children who suffered irreparable neurological disabilities after receiving DPT vaccinations.[6] Breen, *A One Shot Deal*, 41 Wm. & Mary L. Rev. at 315. Increased public awareness spawned lawsuits by injured plaintiffs seeking compensation from DPT manufacturers. By the mid-1980s, the courtroom had become a plaintiff-friendly environment through the expansion of tort remedies available, and the prospect of obtaining extravagant jury-awarded punitive damages against vaccine manufacturers.

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[6] These vaccinations were not the same as the DPT vaccinations currently administered.

Between 1980 and 1986, damage claims for more than $3.5 billion were filed against vaccine producers. Ridgway, *No-Fault Vaccine Insurance*, 24 J. Health Pol. Pol'y & L. at 60-61. As the number of liability lawsuits increased, the number of pharmaceutical manufacturers producing life-saving vaccines diminished rapidly. The "exposure to large damage awards provided the economic justification for companies to stop research and production." Jacobi, *Pharmaceutical Tort Liability*, 38 J. Marshall L. Rev. at 989. Vaccine production became too expensive of an endeavor for these manufacturers to maintain. Increased tort liabilities forced the manufacturers to "reallocate 'an ever larger percentage of revenues from vaccine sales to the costs of insurance and of defending against potential liability.'" La Fetra, *Freedom, Responsibility, and Risk*, 36 Ind. L. Rev. at 650 (quoting John K. Iglehart, *Health Policy Report: Compensating Children with Vaccine-Related Injuries*, 316 New Eng. J. Med. 1283, 1286 (1987)). The cost per dose of the DPT vaccine increased from 11 cents in 1982 to $11.40 in 1986, with $8 of this price going toward liability insurance. *Id.*

Even when manufacturers produced vaccines at increasingly higher costs, they were susceptible to unpredictable future liabilities in the form of punitive damages. Juries were empowered to award massive punitive damages against manufacturers even where scientific evidence was inconclusive as to whether the vaccine had actually caused the injury in question. Elissa Levy, *The Health Act's FDA Defense to Punitive Damages: A Gift to Drug Makers or to the Public?*, 74 Fordham L. Rev. 2425, 2431 (2006). In the mid-1980s, a lawsuit against a manufacturer claiming

that the DPT vaccine caused paralysis in a young boy ended with an award of $1.13 million. *Toner for Toner v. Lederle Laboratories*, 779 F.2d 1429, 1430 (9th Cir. 1986). This award was equivalent to more than half of the entire DPT market. Offit, *Abandoning Vaccines?*, 24 Health Affairs at 622. Although it was later determined that there was no scientific basis to support the claim, pharmaceutical companies were forced to reevaluate their businesses, either withdrawing drugs from the market or leaving the market altogether. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2431. Increasing tort liabilities "diminish[ed] the incentives of a manufacturer to research, develop and produce vaccines" so that within the 1980s, ten of the thirteen companies producing vaccines for five serious childhood diseases left the market. La Fetra, *Freedom, Responsibility, and Risk*, 36 Ind. L. Rev. at 650. It was in response to this public health crisis of massive vaccine shortages and skyrocketing costs that Congress enacted the Vaccine Act.

B. The Vaccine Act Achieved Twin Purposes of Ensuring Compensation to Victims and Limiting Manufacturer Liability

Burdened by the skyrocketing costs of defending vaccine-related litigation, manufacturers became unwilling to fulfill the nation's diminishing vaccine supply. At the same time, victims of vaccine-related injuries complained about the traditional tort law system's uncertain recoveries and the high cost of litigation required to obtain compensatory remedies for injuries. The Vaccine Act was enacted as an answer to both of these concerns. Kapil Kumar Bhanot, *What*

Defines a Public Health Emergency? An Analysis of the Strategic National Stockpile and the National Childhood Vaccine Injury Act: The Need for Prevention of Nonterror National Medical Emergencies, 21 J. Contemp. Health L. & Pol'y 137, 140-41 (2004). The Vaccine Act contained two components: the first was created to ensure the supply and development of vaccines through the National Vaccine Program, and the second was to compensate vaccine-related injuries swiftly and decisively through the Vaccine Injury Compensation Program. *Id.* at 141. These "twin purposes" balanced the public health benefits of widespread vaccination with the risks of vaccine-related injuries. Widespread vaccinations inevitably result in rare but unavoidable injuries from the inherent risk of vaccine-related side effects. The National Vaccine Injury Compensation Program provides victims of vaccinations immediate compensation on a no-fault basis without having to undergo time-consuming determinations of causation on a case-by-case basis. *Id.* At the same time, the National Vaccine Program protects manufacturers by restricting the ability of injured vaccine recipients to bring civil actions for damages. The no-fault compensation program provided an incentive for manufacturers to produce vaccines by shielding them from the potential costs of liability litigation. *Id.* Witnesses before Congress characterized the Vaccine Program as promoting "advances in biotechnology that could lead to the production of new and improved vaccines." H.R. Rep. 99-908, 1986 U.S.C.C.A.N. 6344, 6349).

Overall, the twin purposes of the Vaccine Act work jointly by "creating a remedial system that tries more

quickly to deliver compensation to victims, while also reducing insurance and litigation costs for manufacturers. *Schafer v. Am. Cyanamid Co.*, 20 F.3d 1, 2 (1st Cir. 1994); *see also Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 297 (E.D. Pa. 2007) (The Vaccine Act was enacted "to prevent manufacturers from leaving vaccine production or significantly increasing [its] prices, while at the same time compensat[ing] victims of vaccine-related injuries quickly."). To achieve its purpose of providing immediate recovery to victims of vaccine-related injuries, the Act instituted a no-fault mechanism where vaccine manufacturers are insulated from excessive liability. *Schafer*, 20 F.3d at 4 ("Congress was importantly motivated not only by the desire effectively to compensate side-effect victims, but also by the desire to keep vaccine prices fairly low by reducing compensation costs.") (citing H.R. Rep. 99-908, 1986 U.S.C.C.A.N. at 6345-48).

The twin purposes of the Act work in tandem such that one cannot exist without the other. For this reason, both the immunity for manufacturers and the compensation remedy are bounded. The Act's preemption clause preserves a limited tort remedy against a manufacturer for injuries caused by a vaccine not made according to its FDA-approved formula or that does not provide proper directions and warnings for use. 42 U.S.C. § 300aa-22(b)(1). Likewise, injured victims may not claim compensation under the Vaccine Act while also suing the manufacturers for state tort liabilities arising from their vaccine-related injuries. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2431-32 ("The [Vaccine Act] remove[d] vaccine injury claims out of the

tort system and into a Vaccine Claims court, where the complainants' burdens are eased in exchange for a limited compensation of up to $250,000."). Therefore, to achieve its twin purposes, the Vaccine Act preempts state tort liabilities against vaccine manufacturers from those directly injured by that vaccine, so that the manufacturers may continue producing vaccines and vaccine victims may obtain quick and decisive compensation for their injuries.

The Vaccine Act was designed as a national statutory scheme to best achieve the twin purposes of compensating people injured by vaccines and by encouraging further research, development, and distribution of vaccines that benefit the public health. Compensation of victims without the corresponding preemption of state tort claims would subvert congressional intent by altering the fundamental design and function of the Vaccine Act. This Court should grant certiorari to restore the integrity of the Vaccine Act.

II

GEORGIA'S DECISION TO PERMIT VACCINE DESIGN DEFECT CASES IS AN OUTLIER IN CONFLICT WITH EVERY OTHER COURT, BUT NO LESS DANGEROUS FOR ITS ABERRATIONAL STATUS

A. A Single State Can Cause an Enormous Expansion in Tort Liability

The danger to public health caused by the Georgia Supreme Court's decision should not be understated because this is the first of the state supreme courts or federal appellate courts to rule against preemption in

a vaccine design defect case. History offers many examples of a single expansionist state supreme court causing nationwide ripple effects. For example, the California Supreme Court was a trendsetter in various aspects of tort law. "California recognized new remedies for non-pecuniary injuries, loss of consortium, prenatal injuries, punitive damages, medical monitoring, wrongful life and wrongful birth. Plaintiffs also were permitted to recover against co-defendants under the novel theory of concerted action." Michael L. Rustad & Thomas H. Koenig, *Taming the Tort Monster: The American Civil Justice System as a Battleground of Social Theory*, 68 Brook. L. Rev. 1, 45-46 (2002). *See also Summers v. Tice*, 33 Cal. 2d 80 (1948) (announcing concerted action doctrine later incorporated into the Restatement (Second) of Torts § 433B(d) (1965)); *Greenman v. Yuba Power Prod., Inc.*, 59 Cal. 2d 57 (1963) (establishing strict product liability later incorporated in the Restatement (Second) of Torts § 402A (1965)).

Businesses operating in more than one region of the country suffer economic harm when they must structure their activities and manufacture their products in compliance with differing rules of law in multiple circuits and states. A nationwide manufacturer incurs significant economic costs to avoid liability and to maintain uniformity in its operations by acting in accordance with the law of the most restrictive circuit or state. This Court must step in because otherwise, "'the most restrictive court is effectively binding the nation.'" Robert M. Lawless & Dylan Lager Murray, *An Empirical Analysis of Bankruptcy Certiorari*, 62 Mo. L. Rev. 101, 110-11 (1997) (citation omitted). This practical result runs

afoul of the principle that "a State may not impose economic sanctions on violators of its laws with the intent of changing the tortfeasors' lawful conduct in other States." *BMW of North Am., Inc. v. Gore*, 517 U.S. 559, 572 (1996). Thus, this Court should not wait any longer before resolving the important issue in this case. *Cf. Chamber of Commerce of U.S. v. Brown*, 128 S. Ct. 2408 (2008) (finding federal preemption of state law to avoid patchwork of labor regulation among the fifty states); Respondent's Brief in Opposition, 2007 WL 760217, *20 (2007) (certiorari granted to resolve (disputed) split between Ninth Circuit and Second Circuit, despite respondent arguing that percolation was justified because legislation similar to the challenged California law was pending in fifteen other states and that could result in decision in six additional circuit courts); *Rowe v. New Hampshire Motor Transp. Ass'n*, 128 S. Ct. 989 (2008) (finding federal preemption of state transportation law); Reply in Support of Petition, 2006 WL 3667539, *7 (2006) (petitioner acknowledged that "[n]o other case in the land" interpreted the challenged law as broadly as the First Circuit decision for which certiorari was successfully sought).

B. The Vaccine Act Cannot Survive a Patchwork of State Tort Law

A national preemption scheme is necessary because the risk analysis for vaccines employs a "forward-looking" assessment of future liability for conduct before any potential injury occurs. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 Okla. L. Rev. 135, 135-36 (2005). FDA's regulation of vaccines is different from those of other federal agencies because the FDA must

employ extremely "'specialized experience in assessing risks and control measures,'" which the traditional "'tort system is ill-equipped to handle.'" *Id.* at 136 (citations omitted). Overall, the FDA "'administers the most comprehensive drug regulatory system in the world,'" whose mission is to "optimize the risk-benefit tradeoff by only allowing drugs on the market if they are reasonably safe for their intended class of consumers." *Id.* at 141 (citation omitted). Prescription drugs undergo a rigorous approval process, where the FDA uses its considerable scientific expertise "to balance carefully the risks and benefits of each prescription drug, to understand the inherent risks, and to determine how to craft warnings for allowing each drug to be used safely and effectively." *Id.* at 141. The requirements for approval under the FDA are so extensive that, at the margin, the FDA's regulations probably "over-deter[]," such that "tort liability provides no additional societal benefits." W. Kip Viscusi, *et al.*, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 Seton Hall L. Rev. 1437, 1478 (1994) (regarding FDA's regulation of pharmaceuticals in general). Only 8% of prospective products submitted to the FDA receive approval and enter the American market. Schwartz, *A Prescription for Drug Liability and Regulations*, 58 Okla. L. Rev. at 142.

With the Vaccine Act, Congress singled out the vaccine market to be specially regulated by the FDA and immunized from "regulation through litigation" in tort cases. A national statutory scheme is necessary in order to prevent courts from "co-regulat[ing]" the pharmaceuticals industry through "case-by-case

analysis" of vaccine-related liability. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2435. As with all prescription drugs and pharmaceuticals, vaccines carry an inherent risk of adverse side effects. Breen, *A One Shot Deal*, 41 Wm. & Mary L. Rev. at 313. But vaccines' side effects, in particular, depend largely on the individual recipient, and make them especially unpredictable. *Id.* Because lay juries and judges focus on a specific injury by a sympathetic plaintiff when they impose liability, juries can fail to acknowledge the tremendous benefits vaccines provide as a public health measure. Levy, *The Health Act's FDA Defense to Punitive Damages*, 74 Fordham L. Rev. at 2435, 2449. The FDA, by contrast, conducts a broader risk-benefit analysis that is vital to the survival of the vaccine industry.

A national statutory scheme is necessary to avoid the patchwork of policymaking by individual states in regulating the national vaccine market. Absent federal preemption against the possibility of state tort claims, pharmaceutical companies operating nationwide are subject to differing legal standards because courts throughout the fifty states may answer the same liability questions differently, and "commentators have persuasively argued that the answers to fundamental tort issues change over time within single jurisdictions." Viscusi, *Deterring Inefficient Pharmaceutical Litigation*, 24 Seton Hall L. Rev. at 1477. Consequently, piecemeal legislative reform at the state level will not produce uniform results. *Id.* Such inconsistency and uncertainty over potential liability increases settlement and litigation costs, the very problem the Vaccine Act was intended to avoid. Levy,

The Health Act's FDA Defense to Punitive Damages, 74 Fordham L. Rev. at 2449-50.

In general, the scope of federal preemption is determined by the underlying purpose of the preemption statute, evidenced both by the overall statutory scheme and the background of its enactment. Considered in this context, the Vaccine Act is a national statutory scheme which centralizes the regulatory authority in the FDA. The decision of the Georgia Supreme Court allows its state tort system to subvert the national scheme that Congress created under the Vaccine Act.

CONCLUSION

The Vaccine Act was designed as a national statutory scheme to best achieve the twin purposes of compensating people injured by vaccines and by encouraging further research, development, and distribution of vaccines that benefit the public health. Compensation of victims without the corresponding preemption of state tort claims would subvert congressional intent by altering the fundamental design and function of the Vaccine Act.

The petition for a writ of certiorari should be granted.

DATED: April, 2009.

Respectfully submitted,

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